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DRUG INDUSTRY NEWS

Imports to boost exports

The State Chemicals and Pharmaceuticals Corporation (CPC) has floated incentive schemes for export promotion. Under these schemes, the CPC will supply duty free plastic raw materials and 11 bulk drugs for export production. The following drugs will be made available for the manufacture of formulations: ampicillin trihydrate ampicillin sodium, ethambutol, tetracycline hydrochloride, iodine, gentamycin, trimethoprim, sulphamethoxazole, chloramphenicol powder, palmitate and sodium succinate. CPC has already placed an order for 5,000 kg of iodine and 250 kg of ethambutol which are likely to be available in January and April respectively. Tetracycline hydrochloride will be supplied from its ready stocks. Rest of the items to be imported are under negotiations. The procedural simplicity will enable the small units to take full advantage of the scheme. The raw materials will be provided to units on recommendation by the export promotion councils against submission of duty free advance licences. Working groups composed of representatives of CPC the commerce ministry and export promotion councils will meet regularly to choose items, their quantities and fix prices of the same.

CPC performance in 1978-79

The State Chemicals and Pharmaceuticals Corporation (CPC) showed a decrease of 7.7% in its drug imports (Rs. 423 million) in the year ending March, 1979 over the 1977-78 level. Its exports were up by 15% at Rs. 21 million from the previous year.

The CPC imported mostly from W. Europe. Main sources of imports are listed as below:

Canalised drug imports (in Rs. million) in 78-79

	W. Europe	*E. Europe*	*Asia*
Antibiotics	95.6	30.9	4.8
Antimalarials	49.0	30.1	—
Vitamins	17.2	—	4.9
Antibacterials	3.2	—	8.2
Antihypertensives	—	2.1	—
Other categories	4.0	1.0	0.4
Total	169.0	64.1	18.3

America contributed an import of Rs. 6.1 million.

Bulk drugs export was Rs 1.2 million to West Europe and Rs. 0.1 million to Americas. Total export of formulations was Rs. 21.2 million. Of this East Europe got Rs. 13.5, Africa 4.3, Asia 1.8, West Asia 1.0 and West Europe 0.6 million.

Record output by Hindustan Antibiotics Ltd.

Hindustan Antibiotics Ltd., a state owned penicillin factory at Poona, has achieved a record production during 1978-79. This includes an all time high of 137.56 MMU of first crystals, 100.25 T streptomycin and 4.01 T of ampicillin. The losses slid from Rs. 222.25 lakhs in 1977-78 to 107.16 lakhs for 1978-79.

Glaxo's rights issue: Focus on new issues

Mr. S. Bhoothalingam, Chairman of Glaxo Laboratories announced the issuance of rights shares only to Indian shareholders for further dilution of equity from the present level of 80 per cent, and to raise capital for its future expansion programmes. The company has been waiting for the approval of several projects from the Government for diversifying its activities and manufacture of a number of sophisticated drugs within its competence. Such valuable new drugs are available in the West since long and are imported at a very high cost when prescribed for any Indian patient. Since Indian patent law protects a patent for only 5-7 years as compared to the West where statutory protection extends 14-22 years, it is difficult to import such latest know-how to India. The rate and tempo of dilution of equity will largely depend upon the drug policy of the Government and the pending industrial licences of the company.

CAPEXIL Export Award to Dhrangadhra Chemicals

For its export performance in 1978-79, Dhrangadhra Chemical Works has been given Special Export Award by CAPEXIL. The company is a pioneer manufacturer of basic chemicals since 1939.

A new co-operative drug unit

Alliance Co-operative Pharmaceutical Industries Ltd., the first co-operative of its kind has started functioning in Gujarat. The industry has begun with liquid oral section and has been partly financed by Department of Cottage Industries, Gujarat to the tune of Rs. 1.5 lakhs.

The Governor of Gujarat, while inaugurating, advised the unit to go in for new and cheap drugs and ensure reliability and marketability of its products.

Atul Products—Expansion Programme

A new letter of intent has been granted to Atul Products for the products like H-Acid 300 tonnes, tobias acid 200 tonnes, gamma acid 50 tonnes, J-Acid 50 tonnes and DI-oxy acid 25 tonnes per annum. Besides these, nine new intermediates have been added to the original industrial licence.

Scientific instruments: Move to set up aid centre at Ambala

The Haryana State Industrial Development Corporation has planned to set up a Rs. 2-crore "Prototype Development and Facilities Development Centre" (PDFC), in order to establish proper infrastructure for prototype development and offer facilities for testing and quality control of scientific instruments industry, at Ambala, the biggest centre of electronic and scientific instruments in Northern India. The proposed centre would receive financial assistance from the UNDP and technical assistance from Central Scientific Instruments Organisation (CSIO), Chandigarh. The Centre will assist nearly 600 small units manufacturing scientific and laboratory equipments for school and college laboratories in modernisation, expansion and diversification and will cater to the needs of their foreign and other domestic clients. With the help of the PDFC the annual production of these units is likely to increase from Rs. 60 million to Rs. 250 million with a corresponding increase in export potential from Rs. 18 million to Rs. 60 million from 1981 onwards.

HSD Shortage hits essential Drug units

The recent acute shortage of high speed diesel oil and furnace oil coupled with the continuing power cut has an adverse effect on production programme of the drug and allied industries. If the present crisis persists the country may head for a major shortage of drugs in near future. Owing to want of furnace oil, the bottle manufacturers have not been operating boilers upto their capacity and thus creating scarcity of bottles in the market. With the present rise in prices of all important raw materials, the pharmaceutical industry is already passing through a critical phase.

Gujarat alcohol rules hit Bengal drug units

The production of bulk drugs, vitamin C and laboratory chemicals in West Bengal will be hit if Gujarat methyl alcohol rules (1979) are implemented in toto, according to chemical industry sources. Methyl alcohol is an essential raw material for streptomycin sulphate, tetracycline salts, neomycin and amphotericin and West Bengal gets large quantities of these bulk drugs from Gujarat. If the production of these drugs is stopped the small pharmaceutical companies in West Bengal will be badly affected.

A new source of Diosgenin

Balanites roxburghii a tree found in Thar desert and locally known as Hingota has been found to be a source of Diosgenin, the starting material for corticosteriod sex hormones, oral contraceptives and anabolic agents. The roots and fruits of this plant, counted as an economic plant by UNESCO, yield the sapogenin—the diosgenin. It is reported that the cost of production will be less as compared to the diosgenin obtained from the traditional source *Dioscorea.*

Vitamin C should supplement egg diet

According to Dr. (Mrs.) C. M. Bhat of Haryana Agricultural University, Hissar, eating eggs without Vitamin C hinders the absorption of iron. It is necessary to take fruits like orange, lemons, etc. along with eggs to counter its adverse effects on the absorption of iron.

These findings form a part of the study entitled "Effect of ascorbic acid on availability of iron from an egg-based whole day diet in college girls".

Breast-feeding is not carcinogenic

In the fourth Asian Cancer Conference held at Bombay, Dr. Robert Good of the Sloan Kettering Cancer Centre advised that breast-feeding is necessary for both immunisation and nutrition of the child. Even working women should find time for breast-feeding their children.

Breast feeding does not cause cancer and should not be discouraged in the name of modernisation. Research has shown it to be absolutely safe and a must for ensuring the health of child.

Eosinophil cells damage heart lining

Experts on cardiac muscle diseases now believe that eosinophil cells present in the blood may be responsible for damage to the inner lining of the heart. At the Sixth Asia Pacific Congress on Chest Diseases held at Bombay, it was told that thickening of the inner lining of the heart, known as endomyocardial fibrosis, restricts the contraction and dilation of the heart leading to shortage of breath, puffiness of the face, and swelling of the legs. It may eventually lead to heart failure and death.

Until recently endomyocardial fibrosis was regarded as a disease of the tropics but new work has shown that it may be present in other zones as well. But because of lack of hard data on the incidence and cause of endomyocardial fibrosis, the International Society and Federation of Cardiology has sponsored a multicentre research project in Asia, Americas, Europe and Britain. The centre for India is in Kerala.

The year 1982 has been declared as the year of Tropical Cardiology when an international conference in Bombay will discuss heart problems in the tropics, including rheumatic heart disease and hypertension.

Yoga for defence forces urged

The Indian Science Congress Association has suggested to the Government of India that Yoga should be introduced in defence forces and schools in order to raise efficiency and performance of the same. It has also pleaded for setting up a Physiological and Ergonomical Survey of India for collection and analysis of data on various aspects of science and technology of men at work (ergonomics) with a view to improving the working conditions in agriculture, industry, mining, defence, sports, households and offices.

Underweight kids more alert

According to Dr. S. K. Bhargava and Mrs. I. Datta of the Paediatrics Department of Safdarjung Hospital, low birth weight children develop greater mental alertness and capacity to adjust. Children born underweight are less disoriented and less prone to psychological problems than their healthier counterparts.

The study is based on a clinical assessment of two groups of children born at the hospital and followed up longitudinally to date.

CAT scanners to be installed in India

Computerised Axial Tomography or CAT scanners which locate through a three dimensional image, within a fraction of a millimetre of body, tumours, blood clots etc. are being installed in New Delhi and other major cities of India. A group of overseas Indians in collaboration with the Delhi Neurological Research Institute has initiated a scheme whereby nine brain scanners and three body scanners will be installed.

At present hundreds of Indians have to go abroad, as the only scanner at AIIMS is overworked and one's turn comes only after months. The cost of a brain scanner is about $ 1,60,000 and that of a body scanner $ 600,000. The overseas Indians have deposited with a bank Rs. 1 crore towards the cost of these scanning units.

A trust has been formed to run these units. About 20% of the cases coming for scanning will be treated free of cost Apart from cancer cases, the scanner could be used in cases of head injuries.

Bhatnagar Awards

Dr. V. Sasisekharan of the Indian Institute of Sciences, Bangalore, has been given the Bhatnagar prize in Biological Sciences for the year 1978. The prize for 1979 has been shared by Dr. A. N. Bhaduri, Department of Biochemistry, Jadavpur University, Calcutta with Dr. M. K. Chandrasekaran, School of Biological Sciences, Madurai Kamaraj University, Madurai.

No awards have been given in Medical Sciences for both the years.

ICMR awards

Indian Council of Medical Research (ICMR) has honoured 12 bio-medical scientists with its National awards for the year 1979, for their original and outstanding research contributions. The recipients are:

1. Dr. M. G. Deo of Cancer Research Centre, Bombay, for his work in the field of experimental pathology;

2. Dr. J. K. Sarkar of School of Tropical Medicine, Calcutta, for his contribution in the field of arbovirus and small pox;

3. Dr. S. S. Kaplay of National Institute of Nutrition, Hyderabad, for his work on protein energy malnutrition;

4. Dr. P. N. Shah of Cancer Research Centre, Bombay, for his studies in breast cancer;

5. Dr. R. N. Chakravarti of PGI, Chandigarh, for his contributions in the study of atherosclerosis and thrombosis;

6. Dr. H. Srinivasan of Leprosy Training Institute, Chingleput, and

7. Dr. G. P. Talwar of All India Institute of Medical Sciences, New Delhi, for their respective contributions in the study of reconstructive surgery in leprosy and immunology of leprosy and;

8 Dr. Satyawati Chandra of Industrial Toxicological Research Centre, Lucknow, for her studies on manganese poisoning.

The Shakuntala Amir Chand Prize has been shared by Dr Minati Das of the Indian Institute of Experimental Medicine, Calcutta; Dr. A. N. Malviya and Dr. N. Kochupillai, both from AIIMS, New Delhi, and Dr. H. V. Bhatt of the National Institute of Occupational Health, Ahmedabad.

They have been honoured for their work in the fields of neuropharmacology, clinical immunology, radiation biology and psycho-pharmacology, respectively.

National Industries Fair from Jan. 21

From January 21, 1980, National Industries fair will be held at Pragati Maidan, New Delhi. As many as 21 states and union territories, 11 Central ministries and departments of the Government of India, 25 public sector undertakings, 20 export promotion councils and a large number of manufacturing and trading enterprises in the private sector will be participating in the fair.

Delegates attending UNIDO Conference, being held at the same time, will also be able to have a glimpse of the progress registered by Indian economy as focussed in the fair.

WHO for more of acupuncture

Complaints such as common cold, bronchial asthma, toothache and diarrhoea can be cured by acupuncture, though more research is still needed to develop it. The WHO has urged the Western doctors to take acupuncture seriously and has listed 43 ailments that can be cured through acupuncture.

Western drug firms to change pricing policy

As most of the newest and sophisticated medicines are inappropriate to the needs of the majority population of less developed countries the economic factor shall not, now onwards, be the only factor. What this population needs is mainly antibiotics that are from earlier generation and are generally out of patent.

Previously the firms used to keep the prices of new products very high so as to contribute financially to their continuing research projects. Thus these less developed countries used to get their supplies from non-innovative sources like East European countries where prices were low but quality of the product was not of high standard. But now about 40 such companies have offered to co-operate with WHO in supplying over 150 different medicines at preferential prices to the poorest of these less developed countries.

Scrip, No. **445**, 4 (8 Dec. 79)

Male contraceptive pill—the Chinese way

The Chinese government concerned about the males fathering more than two children has introduced a contraceptive pill for men. It is made from gossypol, a phenolic extract from the cotton wool.

ABPI News No. **176,** 8 (July 79)

A new Polio vaccine

Dr. Jonas Salk, the discoverer of the Salk Polio vaccine has emphasised the need for an effective polio immunisation programme. Dr. Salk's Killed Polio Vaccine (KPV) can be used in controlling the crippling disease as compared to the currently used Live Polio Vaccine (LPV). A single dose of KPV containing a sufficient quantity of antigen is capable of inducing immunity in infants without causing the risk of paralysis. Although the initial cost of KPV is relatively higher than LPV, its advantages over LPV are more in developing countries as LPV is to be preserved in deep-freeze before administration. As a result of lack of refrigeration facilities in remote areas, the vaccine loses its potency.

Blood substitute

A US firm, Sun Oil Co., is developing a compound from oil which acts as a substitute for blood transfusion. It is claimed to be superior to actual blood for it can be sterilised to prevent hepatitis and other infections. It can carry more than twice as much oxygen as blood and does not require refrigeration.

Cromolyn may inhibit histamine secretion

The antiallergic drug cromolyn inhibits histamine release from mast cells that was induced by a classic secretagogue and correspondingly increased incorporation of radio-active phosphate into a 78,000 dalton protein. These effects on histamine secretion and on protein phosphorylation were rapid in onset and both showed tachyphylaxis. Cromolyn may therefore act by altering the phosphorylation of a protein involved in the regulation of secretion.

Science, **207,** 80 (4 Jan. 80)

Alcohol from Cassava

A tropical plant Cassava (*Manihot esculenta*) from Brazil has been found to be a new source of alcohol. A pound of cassava tubers yield three times as much alcohol as sugarcane. The Brazilian Government has built a plant to produce 1600 gallons of alcohol daily.

Pancreas transplanted

Two diabetic patients of the Addenbrookes Hospital, Cambridge, have been given new pancreas in Britain's first successful transplant operations. This could be achieved by an experimental drug and a new surgical method. Both the patients are normal and now will not be dependent upon insulin injections.

Ranitidine, a new H_2-receptor antagonist

Glaxo Group Research Ltd., has reported promising results with Ranitidine, a new H_2-receptor antagonist. Extended trials are now being carried out in several countries and it is found to be more active and more selective in its actions than cimetidine. If the outcome of the studies is good, then drug could be marketed in about three years.

Pharmaceutical J., **223**, 492 (10 Nov. 79)

Recombinant DNA Insulin to be tested on humans

Eli Lilly intends testing recombinant DNA-generated insulin in humans in early 1980. The company will begin testing the insulin within 30 days after filing its investigative new drug application with the US Food and Drug Administration. Lilly anticipates a six month testing period in humans and hopes to market the insulin by 1982.

Scrip, No. **436,** 12 (7 Nov. 79)

A varied DNA molecule structure

Prof. Alexander Rich and his co-workers at Massachusetts Institute of Technology have reported an entirely novel form of DNA molecule which differs significantly from the Double Helix DNA structure proposed by Watson and Crick.

This discovery may give some new information about the development of cancer.

Antitumour agent from Chinese red beans

A highly purified extract of the Chinese red beans has been found to be a source of a new immunostimulant antitumour agent, Abrin. A high molecular weight glycoprotein, Abrin, even when administered in very small doses to animals induces greater immunostimulation and tumour recession than BCG preparations.

Other antitumour agents reported to the general assembly of the Japanese Cancer Association are 5-deoxylfluouridine which when administered orally to mice, was 4 to 6 times more effective than 5-fluorouracil and 3 to 4 times more active than ftorafur against leukaemia and solid tumours. Orally active imidazole cytostatics were also described as being superior to 5-fluorouracil, cytarabine and methotrexate against a variety of solid tumours.

Scrip, No. **439,** 12 (17 Nov. 79)

Man-made bacteria

The case for the issuance of patent for a man made biologically pure culture *Streptomyces vellosus*, a novel micro-organism isolated from soil and used for the production of antibiotic, lincomycin will come up for hearing in US Supreme Court. Previously the court of Customs & Patent appeals had granted the Upjohn, the manufacturing unit, the patent but the Patents office had refused permission. Although the bacteria is not produced by recombinant DNA technique but still the case will have implications for such products.

Scrip, No. **437,** 10(10 Nov. 79)

Cirrhosis cure

Traditional Chinese herbal medicine can cure or markedly improve liver cirrhosis. The Shanxi Institute of Traditional Chinese Medicine has treated patients suffering from chronic hepatitis by administring a decoction developed from a medicament.

Neuroleptics interact with tea and coffee

According to a team of West German doctors, phenothiazines and butyrophenones could interact with tea and coffee. When drops of fluphenazine or haloperidol were added to a solution of coffee or tea, a flanky, insoluble precipitate formed, which is found to contain neuroleptics. They report that 10 per cent of the drug was precipitated, bound or otherwise changed in coffee and about 90 per cent in tea.

A doctor from Charing Cross Hospital, London, has found the above findings clinically very significant as the reaction could result in inactive medication and thus could account for the often observed differences in blood levels of antipsychotic drugs.

Pharmaceutical J., **223,** 280 (1 Dec. 79)

Bronchodilator effect of Cromoglycate

The antiasthmatic drug sodium cromoglycate has a powerful bronchodilator effect, according to a study. The drug is known to stabilise mast cells and inhibit release of mediators of the allergic reaction and thus it is widely used in the prophylactic treatment of asthma but was never regarded as a bronchodilator. But now the study has pointed out that its action is comparable in degree and duration with that of salbutamol.

Pharmaceutical J., **223,** 468 (3 Nov. 79)

Brain chemical discovered

Dynorphin, a new brain chemical of endorphin family, has recently been found. It will help in understanding the complex working of brain and may be used for pain control, mood control and for drug addiction treatment.

These endorphins are similar to opium based drugs and seem to be a major part of the body's chemical defence against pain. Acupuncture is also believed to relieve pain by releasing endorphins in some unknown way.

Early warning of shock

Dr. Dick Stephens of Matter Misericordial Hospital, Canberra, has developed a device which gives surgeons early warning of patients going into shock on the operating table. The device known as tissue perfusion monitor derives information on the circulation of blood by means of a transducer placed on the skin of the patient undergoing surgery. The transducer indicates activity in tiny blood vessels or mucous membrane and transforms the information into electrical impulses which are registered on the machine. This gives doctors warning of a patient going into shock before the skin colour changes or other signs of shock are seen.

Heart patients need exercise

According to Dr. N. Wenger, Professor of Medicine at Emory University in Atlanta, Georgia, heart patients should be prescribed exercise as a medicine. Its dosage should constitute its intensity, frequency and duration. This programme can begin when a person is still recuperating in the hospital.

Once a heart attack victim returns home, a prescribed exerçise programme should continue with medical supervison.

Infection prevention by Cefoxitin

At a symposium in IX World Congress of Gynaecology held at Tokyo, it was reported that antibiotic cefoxitin used prophylactically in patients, undergoing gynaecological surgery, prevents postoperative infections. The drug promises to be a good single antimicrobial agent. At present it is used for the treatment of susceptible infections.

Pharmaceutical J., **223**, 492 (10 Nov. 79)

Postmenopausal flushing

An infusion of naloxone, an opiate antagonist, significantally decreased the number of flushings when given to four women who had severe and frequent postmenopausal flushing. Doctors at a London hospital say that these results provide a strong evidence that flushing is an opiate dependent central mechanism. Further trials to test the long-term effects are underway.

Pharmaceutical, J. **223,** 580 (1 Dec 79)

Cynamid files a counter-claim

In US anti-trust suits filed by India, Iran, Philippines and Kuwait Goverments against US multi-nationals, Cynamid, Pfizer, Bristol Myers, Squibb, Olin and Upjohn, the Cynamid Co. has filed a counter claim against Iran alleging damages resulting from a raise in oil prices by OPEC. These foreign governments have been given the status of US citizens and allowed to sue multinationals for triple damages.

Scrip, No. **442,** 7 (28 Nov. 79)

Gene treatment for sickle cell anaemia

Genex Corporation, a US drug company is working on the commercial application of recombinant DNA for treating sickle cell anaemia by inserting a gene into the blood forming cells found in bone marrow or in blood stream.

No pharmaceutical firm has so far agreed for preliminary developmental work, the yearly cost of treatment will be around $ 4,000 thus making it economically not viable for countries like Africa or India.

Some other uses of recombinant DNA can be to produce the sweetner, aspartame; the anti-coagulant urokinase; various steroid molecules, blood factors including factor VIII; antiviral antigens for vaccine production including against hepatitis B. The development and subsequent production of all these compounds will mean a significant reduction in costs.

Scrip, No. **436,** 7 (7 Nov. 79)

Pre-menstrual tension

In the book 'PMT-the unrecognised illness' its authoress Judy Lever has suggested a remedy for the symptoms which make women depressed and irritable each month before their periods. A 10 mg dose of vitamin B6, taken twice daily from three days before the symptoms would normally arise, until the third day of the period will give considerable improvement. But before starting this treatment it is advisable to consult the doctor.

Pharmaceutical J., **223**, 461 (3 Nov 1979)

Dangerous mistakes in Drug Administration—Price 50 Pence

Medico-Pharmaceutical Forum,
1 Wempole Street,
LONDON, WIM 8 AE

This booklet is a comprehensive account of the steps that should be taken while administering drugs some confusion over names and uses arises, because of many synonyms that are in current use.

ABPI News No. 176, 4 (July 79)

Medicines for the year 2000—Price £ 5

Office of Health Economics, 162, Regent Street
London WIR 6DD

The book is an account of a symposium held at Royal College of Physicians and is edited by George Teeling Smith and Nicholas Wells.

Profits, Politics & Drugs—Price £12

W. Duncan Reekie & Michael H. Weber
The Macmillan Press Ltd., London.

This book is informative and highly readable and together they form a highly potent pharmaceutical pair as they probe a wide spectrum covering, educating politicians and public of the real facts about pharmaceuticals, calling for broad recognition of the industry's contribution to society and presenting a case for defusing the misgiving that drugs are a public danger.

ABPI News No. 176, 3 (July 79)

Medicine-Their correct use—Price Rs. 54

Drs. P. C. Dandiya, J. S. Bapna, and S. K. Patni,
Vision Books Private Ltd.,
36-C, Connaught Place,
New Delhi-110001.

The book is written as a guide to medicine for laymen as well as professionals. Almost all the drugs used for common disorders, their correct use and the need for medical advice have been covered. The book establishes that expensive drugs are not necessarily the better drugs; with knowledge, understanding and discretion significant saving can be effected in medicine bill.

The book is a sort of family guide and is useful for family bookshelf, chronic patients, doctors, pharmacists and others in drugs trade.

Eastern Pharmacist, **22,** 65 (1979)

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DRUGS & PHARMACEUTICALS
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REGULATORY NEWS

Canalised drugs: Special facilities for backward area units

The State Chemicals and Pharmaceuticals Corporation (CPC) under the directive of Union Ministry of Chemicals and Fertilisers has marked special facilities to drug units in backward areas and those set up by graduate diploma holders in professional subjects while distributing canalised drug items. It is equivalent to 15 months requirements against the present 12 months needs. This is to ensure a buffer stock against disruption in the supply of raw materials. CPC will also give preference to these units at the time of actual allocation of canalised drug items especially when their stocks are low.

Government move to ban phenacetin

The Drug Controller has sought industry's view on a move to ban the use of phenacetin, either alone or in combination with other drugs. The drug industry is much surprised over this as banning phenacetin would mean the end of common headache pills like saridon, codopyrin and APC. Phenacetin is usually administered with aspirin, caffeine or codeine.

The drug industry, sore over this reported ban, claimed that phenacetin causes relaxation, euphoria and stimulation and when given in combination with other analgesics it is safer than even aspirin. The withdrawl of the drug is recommended in UK and Canada as this is said to be nephrotoxic. Its use over longer periods would cause kidney failure and certain adverse reactions. Drug manufacturers want adequate time to develop safer substitute if this reported ban is to be implemented finally.

Cancer experts for ban on cigarette ads

In a recent meeting in Bombay, the cancer specialists, including the WHO experts Dr. Higginson, Dr. C A. Lynsell and Dr. Nigel Gray—Director of the International Union against Cancer (WHO)—approved of President Sanjiva Reddy's suggestion of statutory action to ban advertisements for sales promotion of cigarettes and other tobacco products. It is imperative for all specialists, doctors, and medical associations in developing countries to form a strong united front against tobacco companies to fight against health hazards like heart diseases, lung ailments, mouth and esophagus cancer etc. caused by smoking. According to Dr. Nigel Gray only the government can fight against these companies since this is a political problem and can be solved by enacting legislation to stop their sales campaign through the cinema, TV, radio, newspapers and the like.

Inquiry ordered into Glaxo's trading practices

The Monopolies and Restrictive Trade Practices Commission has ordered an inquiry following allegations that Glaxo Laboratories (India) Ltd. is involved in unfair trade in supplying betamethasone. Glaxo is accused of supplying varying quantities of the drug irrespective of orders, phasing supplies, and refusing certain supplies, particularly to a new manufacturer.

These trade practices, it is alleged, tend to prevent, restrict or distort competition among manufacturers using betamethasone, as those receiving larger supplies have a price advantage and those receiving earlier have a time advantage over other competitors.

Moderate saccharine use does not increase cancer risk

An US Food and Drug Administration sponsored study reports bladder cancer risk among heavy artificial sweetener (saccharin and cyclamates) users. In persons who ever use any form of artificial sweetener the relative risk of bladder cancer is only 1%. These findings are not consistent with the earlier studies which suggested a saccharin-bladder cancer risk.

PMA Newsletter, **21**, 1 (24 Dec. 79).

FDA for withdrawl of adult Ilosone only

The U S. Food and Drug Administration's Bureau of Drugs has decided that it will now seek the withdrawl of only adult formulations of erythromycin estolate products instead of asking for withdrawl of all formulations. Paediatric formulations will be kept in abeyance till the deliberation on adult indications are more pronounced.

Scrip, No. **439,** 8 (17 Nov. 79)

West German Pharmacists for ban on drug sampling

Annual general meeting of the W. German pharmacists has urged the German parliament to forbid the manufacture and issuing of samples by law. It said that the existing regulations are inadequate to prevent misuse and guarantee safety, and the samples are not being used as testing material but purely as promotional agents. Moreover the doctors are not following the guidelines concerning storage and issuance of drugs. There are instances in which doctors have given samples whose expiry date has already passed.

Scrip No. **436,** 4, (7 Nov. 79)

Restricted use of barbiturates

Committee on the Review of Medicine, England has advised against the routine use of barbiturates as hypnotics, day time sedatives or as antianxiety agents. The Committee says that barbiturates should only be used for severe intractable insomnia and the oral use of the following barbiturates and their salt is recommended: amylobarbitone, pentobarbitone, butobarbitone, cyclobarbitone and heptabarbitone. The Committee also reported that the benzodiazepine drugs are safer and efficacious alternatives.

As regards indications, contra-indications and addiction potential the Committee says that indications such as tension, tension headache, migraine, hypertension, premature ejaculation, neurasthenia, hysteria, psychosis and amnesia during child birth are inappropriate considering safety and efficacy. Treatment of children, young adults, elderly and debilitated patients, breast feeding or pregnant women or patients with a history of alcohol or drug abuse, uncontrolled pain and porphyria are contra-indications.

The Committee has issued the following warning about the addiction potential:

> Barbiturates have a high addiction potential. Long-term use or use of high dosage for short periods may lead to tolerance and subsequently to physical and psychological dependence. Symptoms of dependence include confusion, defective judgement and loss of emotional control. Withdrawal symptoms occur after long term use on rapid cessation of barbiturate treatment. Symptoms include nightmares, irritability and insomnia and in severe cases, tremors, delirium, convulsions and death. Withdrawal symptoms have been reported in neonates after barbiturate treatment during pregnancy and labour.

Addiction potential of the combination products of barbiturates is also a matter of concern. Dependency and high mortality following overdosage (the dosage determined by the non-barbiturate component may result in overdosage of barbiturate component) are a few of the risks associated with the usage. Also there is insufficient evidence that barbiturate ingredient contributes to the action of the non-barbiturate component.

Pharmaceutical J., **223,** 492 (10 Nov. 79)

FDA cautions about Clinoril, Papaverine and Ilosone

The US Food and Drug Administration has alerted doctors about the use of sulindac (MS&D's Clinoril), ethaverine and papaverine products (Marion's Pavabid) and erythromycin estolate (Lilly's Ilosone).

About papaverine the bulletin says that studies show that about 70% of an oral dose is metabolised in the liver before reaching circulatory system. Thus only 30% of a dose reaches the appropriate site but that too is removed quickly. The FDA's Peripheral and CNS drugs advisory committee has found no evidence for the effectiveness of papaverine and ethaverine for any of their claimed indications.

All solid dosage forms of Ilosone are being withdrawn because of adult hepatotoxicity. Paediatric liquid forms will remain under review to see if they have certain advantages and low enough toxicity for young children. Similarly there are several adverse reaction reports about sulindac (clinoril) showing side effects as shown by indomehacin (Indocin). Most of these reactions occur in association with use of other non-steroidal anti-inflammatory drugs.

Scrip, No. **443,** 14 (1 Dec. 79)

Aspirin for transient ischaemic attacks in men

The US Food and Drug Administration's Peripheral and Central Nervous System drugs advisory committee has recommended aspirin to be included in official indications for certain types of transient ischaemic attacks in men. Aspirin in a daily dose of 1300 mg is safe and effective for reducing the risk of recurrent transient ischaemia attacks in men who have had transient ischaemia of the brain due to fibrin platelet emboli.

Scrip, No. **437,** 15 (10 Nov. 79)

Parke-Davis told to stop Ponstel promotion

The US Food and Drug Administration has told Parke-Davis to stop US promotion of its mefenamic acid product, Ponstel. It is a prostaglandin synthetase inhibitor used in the treatment of dysmenorrhoea. The ban is effective till the Division of Neuropharmacological Drug Products declares Ponstel to be safe and effective for the relief of symptoms of primary spasmodic dysmenorrhoea and till such human chronic safety data necessary for such declaration is submitted and reviewed.

Scrip, No. **440,** 8 (21 Nov. 79)

Hoechst's Merital not sufficiently safe

The US Food and Drug Administration's Psychopharmacological advisory committee has found the data presented by Hoechst on its antidepressant, Merital (Nomifensine) to be not sufficient to demonstrate safety and efficacy. The committee, therefore, recommended a reanalysis of the data.

Scrip, No. **437,** 15 (10 Nov. 79)

GOVERNMENT OF KARNATAKA DRUGS CONTROL DEPARTMENT

(*Monthly Report: October 1979*)

Details of Activities

1. *Licences granted:*	Biological drugs	Non-Biological drugs	Homoeo-pathic	Cosme-tics	Poisons
(*a*) For manufacturing	3	3	—	1	—
(*b*) For sale	61	69	2	—	2

2. *Activities*	Manu-facturing	Sales Establish-ment	Hospital	Drugs (Price Control) Order	Poison
(*a*) Inspections	6	330	13	64	—
(*b*) Contraventions detected	—	7	—	—	—
(*c*) Samples of drugs drawn (*d*) Sample of Cosmetics drawn	—	12	—	—	—
(*e*) Value of drugs destroyed/confiscated	Nil				

3. *Administration*	Manufacturing			Drugs sales establish-ment	Poison
	Drugs	Cosmetics	Homeo-pathic		
(*a*) Licences suspended	—	—	—	4	—
(*b*) Licences cancelled	1	—	—	16	—
(*c*) Licences invalidated	—	—	—	30	—
(*d*) Licencees warned	—	—	—	12	—
(*e*) Applications rejected	—	—	—	6	—

(*f*) Prosecutions launched	(*a*) Drugs and Cosmetics Act	(*b*) Drugs (Prices Control) Order
	2	1

4. *Drugs and Magic Remedies (Objectionable Advertisements) Act*

(*a*) Advertisements scrutinised	— 310
(*b*) Prosecutions launched	— Nil
(*c*) Contraventions detected	— 2
(*d*) Warnings issued	— Nil

5. *General Remarks:—*

The Drugs Inspector, Bellary Division, Bellary, seized drugs which were of substandard quality. Two cases ended in conviction, launched earlier by the Deparment. Nine complaints under the Drugs and Cosmetics Act, 1940 and rules thereunder and 9 complaints under the Drugs (Prices Control) Order, 1979 were received and are under investigation. During this month 4 cases under the Drugs and Cosmetics Act, 1940 and 5 cases under the Drugs (Prices Control) Order, 1970 were investigated.

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INDUSTRIAL LICENCES ISSUED DURING SEPTEMBER, OCTOBER 1979

Sl. No.	Name & address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
LICENCES					
1.	Abbott Laboratories India Pvt. Ltd., Jehangir Building, 133, Mahatma Gandhi Road, Bombay 400023.	Bombay	(i) Citric acid mixture powder (ii) Kaolin mixture with pectin	6000 Kgs 5000 litres	New Article
2.	Boehringer-Knoll Ltd. United India Building, P. Mehta Road, Bombay 400001.	Bombay	(i) Theophylline (ii) Aminophylline (iii) Hydroxyethyl theophylline	40 T 30 T 10 T	New Unit
3.	Boots Company India Ltd., 17, Nicol Road, Post Box 680, Bombay 400038.	Bombay	Ibuprofen	6 T (existing) 15 T (after expansion)	Substantial expansion
4.	E. Merck India Pvt. Ltd. Shiv Sagar Estate 'A', Dr. Annie Besant Road, Worli, Bombay 400018.	Bombay	Refined Papain	50 T	New Article
5.	Gujarat Industrial Investment Corporation Ltd., 4th Floor, Natraj Chambers, Ashram Road, Ahmedabad-9.	Ahmedabad	(i) Ethambutol HCl (ii) DL-2 Aminobutanol/ D-2-aminobutanol	50 T 125 T in terms of DL-2-aminobutanol	New Unit

Contd.

Con td.

Sl. No.	Name & address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Typeof Licence
6.	Hindustan Antibiotics Ltd., Pimpri, Pune 400018.	Pune	Insulin Plain Injection 40 units per ml	10 lakh vials 10 ml each	New Article
			Vials	1208 lakh nos (additional)	Substantial expansion
				1748 ,, ,, (after expn.)	
			Capsules	1591.64 ,, ,, (additional)	
				1771.64 ,, ,, (after expn.)	
			Tablets	9095 ,, ,, (additional)	
				9275 ,, ,, (after expn.)	
			Ampoules	488 ,, ,, (additional)	
				488 ,, ,, (after expn.)	
			Ointment tubes	1013 ,, ,, (additional)	
				1013 ,, ,, (after expn.)	
			Oral syrup bottled	4805 ,, ,, (additional)	
				4805 ,, ,, (after expn.)	
			This additional formulation activity will be based on the following antibiotics/drugs		
			Penicillin	60 MMU	
			Erythromycin	19 T	
			Streptomycin	60 T	
			Ampicillin and semisynthetic penicillin	12 T	
			Chloramphenicol	25 T	

Contd.

Contd.

Sl. No.	Name & address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			Vitamin C	62.5 T	
			Aminoglycosidic antibiotics like Neomycin, Kanamycin and Gentamycin	18 T	
			During September		
7.	Indian Drugs and Pharmaceuticals Ltd. N-12, South Extension, Part I, Ring Road, New Delhi 110049.	New Delhi	(i) Antidiarrhoeal (Syrup-60 ml bottles)	18 kilo litres	New Article
			(ii) Diphenyl hydantoin (Caps-100 mg)	190 lakh nos	
			(iii) Antispasmodic anticholinergic (Tabs-25 mg)	130 lakh nos	
			(iv) Antispasmodic anticholinergic (Drops-10 ml)	250 litres	
			(v) Antispasmodic anticholinergic (Injection-2 ml)	1.8 kilo litres	
			(iv) Antispasmodic anticholinergic (Injection-30 ml)	500 litres	
			(vii) Antispasmodic anticholinergic (Injection 30 ml)	9 kilo litres	
			(viii) Enzyme (Tabs-2.5 mg)	220 lakh nos	

Contd.

Contd.

Sl. No.	Name & address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			(xi) Enzyme (Syrup 100 ml bottles)	93.5 kilo litres	
			(x) Glybenclamide (Tabs-5 mg)	90 lakh nos	
			During October		
			Tablets		
			(i) I. N. H. (100 mg)	50 million	
			(ii) I. N. H. (800 mg)	20 ,,	
			(iii) I. N. H. Thiacetazone	25 ,,	
			(iv) Aspirin	40 ,,	
			(v) A. P. C.	40 ,,	
			(vi) Iodochlorohydroxyquinoline	20 ,,	
			(vii) Phenylbutazone	2 ,,	
			(viii) Ferrous sulphate	10 ,,	
			(ix) Folic acid	10 ,,	
			(x) Digestive enzyme	5 ,,	
			(xi) Vitamin B-complex	10 ,,	
			(xii) Vitamin C	25 ,,	
			(xiii) Multivitamin	10 ,,	
			(xiv) Chlorpromazine	1 ,,	
			(xv) Prednisolone	2 ,,	
			(xvi) Antacid	10 ,,	
			(xvii) Phthalyl sulphathiazole	25 ,,	
			Ampoules		
			(i) Distilled Water	7.5 ,,	
			(ii) Dextrose (5%)	1 ,,	
			(iii) Analgin (5 ml)	0.5 ,,	

Contd.

Contd.

Sl. No.	Name & address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			(iv) Pethidene (2 ml)	0.5 million	
			(v) Ephedrine (1 ml)	0.5 ,,	
			Powder Vials		
			(i) Streptomycine sulphate	10 ,,	
			(ii) Procaine penicillin	5 ,,	
			(iii) Streptopenicillin	5 ,,	
			Capsules		
			(i) Tetracycline	5 ,,	
			(ii) Oxytetracycline	5 ,,	
			Liquids		
			(i) Piperazine citrate	20 k l.	
			(ii) Cough syrup	30 ,,	
			(iii) Vitamin B-complex syrup	30 ,,	
			(iv) Milk of magnesia	15 ,,	
			(v) Tincture iodine	25 ,,	
			(vi) Liquid glycyrrhiza	10 ,,	
			(vii) Chloroform spirit	30 ,,	
			(viii) Tincture cardamom	30 ,,	
			(ix) Tincture benzoin	20 ,,	
8.	Ranbaxy Laboratories Ltd., 78, Nehru Place, New Delhi 110019.	New Delhi	(i) Pineadol (pindolal formulations) (NA)	45.00 kgs	New Unit
			(ii) Diabrim (chloroquin phosphate) (NB)	505.575 ,,	

Contd.

Contd.

Sl. No.	Name & address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			(iii) Melubrin (chloroquin phosphate) (NA)	8612.555 kgs	
			(iv) Ampen (amoxycillin formulations) (NA)	2003.160 ,,	
			(v) Nemoten (naproxen formulations) (NA)	551.200 ,,	
			(vi) Penigee (penicillin formulations) (NA)	6615.000 ,,	
			(vii) Sulphamethizole (Formulation sulphex) (NA)	5513.000 ,,	
			(viii) Sulphed (sulphadimidine formulations) (NA)	2756.500 ,,	
			(ix) Ranphenicol (chloramphenicol sodium succinate formulations) (NA)	1000.000 ,,	
			(x) Oxyn (Oxytetracycline HCl formulations) (SE/NA)	12781.510 ,,	
			(xi) Ascor (VitaminC formulations) (NA)	14511.500 ,,	
9.	Shri R. K. Poddar, 4, Camac Street, Calcutta 700016.	Calcutta	Diglyceryl ethers of bisphenol-A	300 T	New Unit

Contd.

Contd.

Sl. No.	Name & address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			Tablets		
10.	Smith Stanistreet & Co. Ltd. 18, Convent Road, Calcutta 700014.	Calcutta	(i) Ethambutol IP/BP/USP	2,500 million	New Article
			(ii) Propranolol IP/BP/USP	5,000 ,,	
			(iii) Metronidazole IP/BP/USP	8,000 ,,	
			(iv) Anti-asthmatic	8,000 ,,	
			(v) Ampicillin granules for syrup bottles contg. 2 gm ampicillin	0.250 ,,	
			(vi) Antibacterial	5,000 ,,	
			Capsules		
			(i) Hematinic	5,000 ,,	
			(ii) Rifampicin 250 mg	4,000 ,,	
			Injectables		
			(i) Sulphadimidine sodium $33\frac{1}{3}\%$, 500 ml	0.036 ,,	
			(ii) Sulphadimidine sodium $33\frac{1}{3}\%$, 500 ml	0.036 ,,	
			Miscellaneous Preparations		
			(i) Sulphadimidine sodium 16%, 500 ml	0.012 ,,	
			(ii) Cetrimide compound lotion 1 lt. bottle	0.045 ,,	
			(iii) Contraceptive cream/Jelly 100 gm tube	1,000 ,,	

Contd.

Contd.

Sl. No.	Name & address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			Bulk Drugs		
11.	Tamil Nadu Dadha Pharmaceuticals Ltd. 10, Jeyporenagar, Madras-86.	Madras	(i) Dexamethasone	110 kg	Substantial expansion
			(ii) Triamcinalone	40 ,,	
			(iii) Betamethasone	20 ,,	
			(iv) Prednisolone	500 ,,	
			Chemicals		
			(i) Lactic acid	120 T	
			(ii) Calcium lactate	60 T	

* * * *

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NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
1.	*Anaesthetic*			
	Etomidate	Hypnomidate	Ethnor	S. Africa
2.	*Antacid*			
	Alginic acid/antacids	Meracote	Merrell	Australia
3.	*Antianginal*			
	Glyceryl trinitrate ointment	Nitrobid	Marion	Switzerland
4.	*Antibacterial*			
	Cefoxitin	Mefoxitin	Merck, Sharp & Dohme	Switzerland
	Josamycin	Josacine	Pharmuka	France
5.	*Anticonvulsant*			
	Sodium valproate	Depakene	Abbott	Brazil/Chile
6.	*Antidepressant*			
	Mianserin	Athmyl	Organon	France
7.	*Antihypertensive*			
	Labetalol	Trandate	Glaxo	Switzerland
	Prazosin	Minipress	Pfizer	France/ Nigeria
8.	*Anti-inflammatory*			
	Diclofenac	Voltaren	Geigy	Israel
9.	*Antineoplastic*			
	Dacarbazine	DTIC	Dome	Sweden
10.	*Antispasticity agent*			
	Dantrolene	Dantrium	Oberval	France
11.	*β-Blocker*			
	Nadolol	Corgard	Squibb	Brazil

Contd.

Contd.

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
12.	*GI Regulator*			
	Bromopride	Cascapride	Cascan	W. Germany
	Domperidone	Motilium	Cilag	Switzerland
13.	*Hypoglycaemic*			
	Gliclazide	Diamicron	Servier	Switzerland
14.	*Keratolytic*			
	Tretinoin	Aberel	Ethnor	Australia
15.	*Mucolytic*			
	Letosteine	Viscotiol	Carlo Erba	France
16.	*Mucolytic/bronchodilator*			
	Acetylcysteine + isoprenaline (isoproterenal)	Mucomyst with isoproterenal	Mead Johnson	USA
17.	*Spasmolytic*			
	Pirenzepine	Gastrozepine	Boehringer	Switzerland
18.	*Topical antifungal*			
	Tolnaftate + nystatin	Duoderm	Scherag	S. Africa
19.	*Tranquilliser*			
	Clobazam	Urbanyl	Diamant	Kenya
	Clobazam	Urbanyl	Hoechst	Switzerland
	Clorazepate	Mendon	Dainippon	Japan

* * * *

DRUGS & PHARMACEUTICALS
PATENTS AWARENESS BULLETIN

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INDIAN INSTITUTE OF EXPERIMENTAL MEDICINE, CALCUTTA

A PROFILE

The IIEM, Calcutta, an institute taken over by Council of Scientific and Industrial Research in 1956 is conducting research in basic biological sciences with an emphasis on current biological and medical needs of the country. The projects at the Institute have been grouped into Biochemical Engineering, Enzyme Engineering, Medicinal Chemistry and Experimental Medicine.

Some major projects under these programmes are: (*a*) conversion of psychotrine to dehydroemetine, (*b*) bulk isolation of glucagon from slaughter house wastes and its regulatory role in carbohydrate metabolism, (*c*) fermentative method for large scale production of methionine, (*d*) experimental Parkinsonism using "oxotremorine model", (*e*) production of enzymes of industrial importance from microbial sources, and (*f*) extraction of steroids and terpenoids of importance to industries from indigenous medical plants.

The projects currently going on in the Institute are:

1. **Biochemical Engineering:** The Institute has prepared a number of biochemicals for which methodology has already been developed and work on developing methodology for neuraminidase, cholera enterotoxin, HCG, placental enzymes, asparaginase etc., is in progress. The raw materials utilised are mainly hospital wastes like umbilical cord, placenta etc., agricultural products like *Canavalia ensiformis* and *Ricinus communis* and slaughter house wastes like pig blood.

2. **Enzyme Engineering**: Development of diagnostic aids based on the use of immobilised enzymes, e.g. glucose-oxidase strips and immobilised urease for the estimation of urea is in progress. In view of the simplicity of the technique, it is ideally suited for use in rural health centres and in urban areas and will reduce the cost of diagnostic services. Development of drug and enzyme delivery systems based on the use of liposomes incorporating glycolipids or antibody to cell-specific antigens on their surface so as to target them to particular tissue which are diseased was carried out in respect of the liver cells. Such systems of drug delivery will help to improve the therapy of diseases like viral hepatitis and cancer and also minimise side effects.

Enzyme linked immunoassay system for rapid diagnosis employs enzyme-labelled antibodies (in matrix-bound form) to detect circulating soluble antigens and antibodies for the diagnosis of parasitic diseases like malaria, filariasis etc., whose diagnosis at present involves laborious procedure.

3. A project which has been reoriented and extended in scope relates to the study of mental retardation caused by inborn metabolic defects in the eastern part of

the country. The aim is to study the pattern of incidence of genetically mediated mental retardation in this area, develop techniques of rapid diagnosis applicable to patients as well as at the prenatal stage and develop an advisory health care service to help retarded children and also provide genetic counselling to expectant mother whose offspring may be at risk. The study covers genetic defects of aminoacids and glycoconjugates. On the clinical side the Bangur Institute of Neurology and the Departments of Pathology and Paediatrics of the Institute of Post Graduate Medical Education and Research, Calcutta, are collaborating in the programme.

Two processes developed at the Institute and ready for commercial exploitation are as under:—

Kallstroemia pubescens:

Diosgenin is a precursor of steroid drugs for oral contraceptives. At present 50% of the demand for diosgenin in India is met from Dioscorea yams growing in the hilly areas of Kashmir and Himachal Pradesh. The Institute has discovered *Kallstroemia pubescens* (G. Don) Dandy (Zygophyllaceae) to be a good alternate source for industrial production of diosgenin. It is an exotic weed, but its luxuriant growth in many areas in Gangetic West Bengal suggests that the plant can be grown in the vast Indian plains. It has some advantages over other sources of diosgenin. For example, it can be grown at least three times a year. Its cultivation, collection and processing are also easier. A project involving Indian Institute of Experimental Medicine, Calcutta; National Botanical Research Institute, Lucknow; and Regional Research Laboratory, Bhubaneswar, has been taken up to work out agrotechnology and economics of cultivation of the plant. In collaboration with the Forest Department, Government of West Bengal, the plant is also being cultivated at different agro-climatic conditions to find out the yield of diosgenin per acre.

Lectins

The Institute has developed a simple and rapid method for isolating lectins in large amounts. At present the lectins are wholly imported at exorbitant price. Already some of the lectins prepared by the method developed by the Institute have been exported.

Lectins (phytohaemagglutinins), sugar binding proteins, have found widespread applications in biomedical sciences for blood typing, detection of chromosomal abnormalities; analytical biochemistry and cell and molecular biology.

Address: Indian Institute of Experimental Medicine,
4, Raja Subodh Chandra Mullick Road,
Calcutta 700 032

Gram: LIVING CELL
Phone: PBX 46-3491
Telex: 021-7108

Publications of
The Economic Botany Information Service
National Botanical Research Institute
LUCKNOW-226001
INDIA

The Economic Botany Information Service of the National Botanical Research Institute, Lucknow has brought out, during 1979, a few extension bulletins covering a wide spectrum of research being done at the institute, a world bibliography on 'Pan' *Piper betle* Linn. and a compilation on 'Herbal Drugs in Indian Pharmaceutical Industry' covering 542 plant species.

These bulletins are intended to carry the economically useful results of the NBRI research to the ultimate user.

Extn. Bull. No. 1 : DHAINCHA FOR SEED GUM—1979—Rs. 4.00

Describes the studies made by the NBRI on 'Dhaincha' (*Sesbania bispinosa* (Jacq.) Fawcet & Rendle (Syn. *S. aculeata* Pers) and establishes the feasibility of its seeds as a source of a commercial gum.

Extn. Bull. No. 2: DEHYDRATION OF FLOWERS AND FOLIAGE—1979—Rs. 6.50

This bulletin describes new techniques developed by the NBRI for dehydration and preservation of 16 well-known flowers and foliage. The dried flowers and foliage can be utilized in a variety of ways, such as for wall hangings and frames, paper weights, and greeting cards. The bulletin gives instructions for preparing greeting cards and floral arrangements and is useful for hobbyists as well as for an off-beat cottage industry.

Extn. Bull. No. 3 : 'DAMASK' ROSE FOR ROSE OIL & ROSE WATER—1979
Rs. 6.60

Agrotechniques developed for cultivation of Damask Rose (*Rosa damascena* Mill.) and a field distillation unit, developed by the NBRI for the production of Rose oil and Rose water, have been described. Techno-economics of cultivation and products therefrom have also been given.

Extn. Bull. No. 4 : MATRICARIA FOR BLUE OIL—1979—Rs. 4.00

Describes the agronomical studies, on German or Hungarian or Small Chamomile (*Matricaria chamomilla* Linn.), the flowers of which yield an aromatic oil, known as Blue oil used in medicine and as a flavouring agent The NBRI has successfully established the plant as a crop of industrial importance on marginal soils and the information given in this publication includes the techno-economics of cultivation and products therefrom.

Extn. Bull. No. 5 : CONTROL NOXIOUS ALGAE IN GARDEN TANKS AND PONDS—1979—Rs. 5.15

This bulletin describes various chemical control measures for 21 genera of Blue-Green and Green algae as well as Diatoms which usually grow wild in water reservoirs, garden tanks, ponds, etc. in such large proportions that their 'mats' or 'blooms' not only make these water bodies unsightly and foul-smelling, but also unserviceable. This booklet is of much practical use to the garden enthusiasts and to those concerned with management of water reservoirs.

Extn. Bull. No. 6 : MASS PROPAGATION OF DIOSCOREA FLORIBUNDA BY TISSUE CULTURE—1979—Rs. 6.00

The method evolved by NBRI for rapid clonal multiplication, through tissue and organ culture of *Dioscorea floribunda* has been described. Profusely illustrated, this bulletin is of much interest to the research scientists, the cultivators of medicinal plants and the pharmaceutical industry.

BIBLIOGRAPHY ON PAN—*Piper betle* Linn —1979—Rs. 19.00

This bibliography lists 593 references, pertaining to different aspects of cultivation of and trade in 'Pan' which are distributed under 10 broad heads, such as, Morphology and Taxonomy, Cytology and Embryology, Pharmacognosy and Pharmacology, Cultivation, Diseases and Pests, Packaging and Storage, etc.. Under each 'head', the references are arranged chronologically and alphabetically. An Author-Index is also appended.

HERBAL DRUGS IN INDIAN PHARMACEUTICAL INDUSTRY—1979—Rs. 14.00

This bulletin lists 542 botanical species, employed as drugs, in 1674 formulations, marketed by 160 pharmaceutical concerns and covers Ayurvedic, Unani, Siddha and Allopathic systems of medicine. It has 4 indices, giving common English, vernacular and trade names of the drugs, as well as botanical names of the drug plants and a consolidated list of the pharmaceutical concerns listed in the publication.

These publications are available from :
The Head,
Economic Botany Information Service,
National Botanical Research Institute,
Lucknow—226001, India.

CIMAP'S PUBLICATION

Current Research on Medicinal and Aromatic Plants

The title publication, a quarterly bulletin, has recently been started by the Information Division of the Central Institute of Medicinal and Aromatic Plants, Lucknow. The bulletin abstracts papers on medicinal and aromatic plants and essential oils in the fields of agronomy, genetics, plant breeding, physiology and biochemistry, phytopathology, entomology, botany and pharmacognosy, medicinal plant chemistry, essential oil chemistry and processing technology.

Information on import/export and current Indian and foreign prices of important essential oils, aromatic chemicals, vegetable drugs, spices, alkaloids and also the requirements of crude drugs and essential oil by industry are some of the other areas covered by this bulletin. Relevant news items from newspapers, information about forthcoming seminars, symposia, new periodicals and books are also being covered.

It also includes reviews and bibliographies on important medicinal and aromatic plants and essential oils.

For subscription write to :
Sri O. P. Virmani,
Industrial Liaison Officer,
Central Institute of Medicinal
& Aromatic Plants (CIMAP),
474/6, Sitapur Road,
LUCKNOW 226007

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Others	Rs. 45	£5 0	$10.0	Rs. 12	£1.50	$3.0

DRUG INDUSTRY NEWS

Indian systems of medicine to get a boost

As a part of the programme "Health for all by 2000 AD", Union Government has drawn up a Rs. 60 crores scheme during the current plan period to develop Indian systems of medicine.

Central Council for Research in Ayurveda and Siddha (CCRAS) is emphasising on community health care research, particularly in tribal areas to revive the herbal cure system. It has also intensified its door-to-door survey and surveillance to set up a close link between the research team and the community.

Giving the slogan "Placing people's health in people's hands" the Council has undertaken clinical research on various diseases. It has also decided to upgrade some regional ayurveda research institutes to regional research centres which will transfer laboratory results to the country. Collection of flora from different forests of the country has also been started by the council.

Aluminium foil shortage: Government allows bottle packing

In view of the continuing shortage of aluminium foils the Union Government has permitted drug units to pack tablets in bottles provided the price of drugs is not changed. This facility to bottle-pack tablets has been given till June 30, 1980. The manufacturers are also required to ensure that the therapeutic value of drugs is not affected because of the change in packing.

The above directive is in response to the drug industry's appeal to Union Ministry for Petroleum and Chemicals for allowing the pharmaceutical units to import aluminium plates and sheets as there is an acute shortage of these items in the country at present. Because of the shortage of commercial grade aluminium sheets and plates, collapsible tubes could not be manufactured in sufficient quantity to pack certain drugs. Besides, some units packing their drugs with aluminium seals, taggers and pilfer-proof aluminium caps could not manufacture these drugs due to this shortage.

CPC orders on cut in validity period upset Drug units.

The Chemical and Pharmaceutical Corporation of India's orders on the reduction in the validity period for lifting of canalised raw material, from 90 to 35 days has perturbed the drug industry.

CPC has reportedly taken the decision in view of the slow lifting and the resultant heavy inventories. Indian Drug Manufacturers Association (IDMA) has contested CPC action and pointed out that high inventories are due to CPC's shortcomings and non-lifting of quota by Indian Drugs and Pharmaceuticals Limited, a Government undertaking.

Paracetamol export

The Union Government is considering a proposal for a 20 per cent cash subsidy on export of paracetamol as India is now in a position to export about 1,500 tonnes of it, per annum, after meeting the total indigenous demand.

The role of paracetamol as "pain killer" with no side effects has been recognised all over the world. India which was an importer of this drug barely a decade ago is now in a position to export it.

Human skin grown in lab

Scientists at the Massachusetts Institute of Technology (MIT) have developed a method for growing large amounts of human skin in the laboratory. The grown skin may find use as grafts to replace damaged skin. Experiments involving implantation of human skin cells on mice have shown that these cells grow well in the new host; the host mice are however pretreated so that they do not reject foreign materials. The MIT biologist, Howard Green, points out that they are in a position to grow large amount of skin if it proves useful for human patients. According to him, an injured person's own cells could be grown into large pieces of tissue within five weeks. And this tissue could be grafted to cover a severe burn or injury.

Influenza vaccine

Scientists working at Searle's Research Laboratory, UK, have made progress towards developing a vaccine that they hope will ultimately combat all known strains of influenza. Such a universal vaccine would prevent epidemics like Russian flu, Hong Kong flu and Brazilian flu. The vaccine could be in the market by the middle of this decade.

Laser surgery for treating infertile women

A technique using a laser beam to open blocked fallopian tubes offers hope to infertile women who want to have babies.

Dr. Joseph Bellina, Head, Laser Research Institute, New Orleans, USA, who has used this technique told the International Congress of Gynaecological Laser Surgery that though it is still in an experimental stage it has tremendous promise. Of all the operations done so far, in about 80 per cent women it was successful as they could bear children.

Thioproline : A new cancer drug

According to a study published in the *Lancet*, a Spanish doctor, Dr. Mario Gosalvez, has discovered a new cancer cure which, if further tests prove positive, would radically alter the treatment of cancer. The drug called thioproline converts cancer cells back to normal instead of killing them.

Dr. Gosalvez was trying for a drug which would prevent cancer cells from multiplying and forming a lump when they come into contact with other cells, because normal cells stop growing when they touch each other.

Queen bee's diet for longevity

Queen bee's life-span of five years as compared to only three months life of labour bees might be because of her vitamin rich royal jelly diet. This jelly could provide the key to a means of lengthening human and animal life-span.

Dr. Gardener, an industrial chemist from New Jersey, USA, has found that the life of the insects could be extended by as much as 40 per cent by feeding them on this jelly.

Surgery through laser

According to Dr. Warner Rother of Germany a laser beam of 100 watts can be used for sophisticated surgery. The light is transmitted through a flexible optical fibre chord made of quartz inserted into a instrument which directs the light beam on the tissue.

The light energy is absorbed by the tissue and converted into heat energy. This results in coagulation of the tissue as the temperature of the irradiated tissue goes up to 57°. This process can be used for the control of severe haemorrhage or destruction of tumours. It also enables the application of beam with an endoscope in the control of massive bleeding in the oesophagus or stomach or to treat tumours.

Horse serum antibody for cancer cure

According to Prof. H. Hirai and his co-workers of Hokaido University, cancer of liver and reproductive organs can be cured by using an antibody from the horse serum.

This treatment takes its cue from a discovery that a large amount of alpha-fetoprotein (AFP) is secreted in persons suffering from embryonal cancer affecting the reproductive organs or the liver. AFP is normally found in the foetus and not generated by man after birth. The researchers obtained the anti-serum by injecting AFP into a horse.

A 15-year old girl suffering from embryonic ovary cancer was given this antiserum twice to bring the AFP level in her blood down to normal and then given anticancer medicine. She has recovered and has no signs of cancer. Nine-tenth of persons suffering from embryonic cancer die within six months and the antiserum is a major breakthrough, the scientists claim.

Drug resistance in bacteria on increase

Drug resistant bacteria have spread far and wide in the country. A three day conference on the problems posed by drug resistant bacteria was organised jointly by Lady Hardinge Medical College (LHMC) and University Grants Commission in New Delhi in January. According to Dr. K. B. Sharma, Chief Microbiologist, LHMC, the problem is of concern because the antibiotics which were until recently a panacea for bacterial diseases are now proving futile in their treatment. Reports of antibiotic resistant cases of dysentery and diarrhoea have come from several states. Study of salmonella—the causative organism of typhoid and other intestinal diseases—at the Salmonella Centre at LHMC has revealed that its several strains have acquired resistance to antibiotics thus posing problem of treatment particularly in infants. Drug resistant strains of typhoid germs were first detected in India, in Kerala, in 1972. Chloramphenicol the standard antibiotic against typhoid is no longer useful in treatment of typhoid cases caused by the resistant strains. The resistant strain of *Salmonella typhimurium* have now spread to Madras, Poona, Bombay, Calcutta, Vellore, Mysore, Hissar, Pantnagar, Calicut, Manipal and Belgaun. An outbreak of dysentery near Vellore was caused by *Shigella* germs which were resistant to antibiotics. Sixty-five strains of *S. aluchua* isolated during an epidemic in Calcutta were resistant to multiple drugs and these have now spread to Bombay. Other drug resistant salmonellae that were found are *S. wien*, *S. anatum* and *S. paratyphi*. Spread of strains. of *S. newport* in Delhi hospitals some times back had lead to the death of 80 infants. The strains were found to be resistant to five antibiotics including ampicillin and chloramphenicol.

According to Dr. E. S. Anderson from Britain the antibiotic resistance has emerged due to indiscriminate use of antibiotics and has become a problem in developing countries where there is no control on the sale of antibiotics.

New fluorescent reagent for enzyme detection

Chemical Dynamics Corporation of USA has recently introduced a fluorescent reagent useful in the preparation of numerous fluorogenic substrates. The reagent, 7-aminomethyl coumarin, has a high degree of fluorescence that permits easy detection of even microgram quantities of chymotrypsin, trypsin, elastase and urokinase. It is reported that substrates prepared using this chemical are quite specific and sensitive.

Papain production a viable Agro-Industry

The milky latex papain, exudate of papaya fruits, is much in demand abroad for manufacturing drugs for relieving stomach disorders, in breweries for clarifying beer, in the leather and tanning industry for softening leather, in tenderizing meat and in the manufacture of cosmetics. In Maharashtra and Gujarat states papaya growers are already exploiting this opportunity fully. Even the papaya leaves are in great demand for leather and meat industries.

For the collection of latex, near ripe papaya fruits are selected and 2 mm deep cuts made running down the length of the fruit, at distances 3 cm apart. The latex is collected in aluminium trays, dried and then scrapped. The drying is done in sun or in ovens at temperature below 38°C. The dried latex is powdered and packed in polythene packs. The product sells at Rs. 60 to 80 per kg. A papaya plantation is estimated to yield 200 kg papain per hectare in the first year, 100 kg in the second year and 50 kg in the third year. The crop is, however, uneconomical after three years. Net profit at the cost of Rs. 80 per kg of papain for a period of two years is estimated to be Rs. 10,000 per acre. The fruits after latex extraction remain edible and fit for use in jams and candies. Papain production is a viable agro-industry. Suburbs of large cities are ideal for papaya plantation for, besides latex, fruits will also have a good market.

Polymers find many uses in medicine

Polymer hydrogen is an effective male contraceptive. This finding was reported by a group of scientists from All India Institute of Medical Sciences, New Delhi, at the sixth International Symposium on "New frontiers in polymer science and polymer applications" held at Madras recently. The polymer is injected into vas eferens where it increases hydrogen concentration and thus the resulting acidity kills the spermatozoa passing through it. A study has been conducted on rats which proves polymer hydrogen to be useful in fertility control. The advantages of this method are that it is non-surgical, non-occlusive and reversible. According to a paper presented by West German scientists, carbon fibre reinforced polymer composites are good biocompatible materials for substituting metallic bone plates traditionally used in fixation of fractured bone parts. The polymeric material, unlike the metallic plates, can be tailored to the elastic and strength requirements of the bone with advantages that it promotes bone regeneration and avoids osteoporosis and bone degeneration. Several areas in which polymers have already made significant progress are hemodialysis membrane, drug carriers, contact lenses and artificial organs.

Their other applications are as adhesive material for repair and replacement of diseased or damaged body parts. The alkyl 2-cynoacrylates are widely approved of as soft-tissue adhesives as they form covalent bonds to protein and polymerise in seconds. Two scientists in Australia have devised techniques, one of them using aqueous polycarboxylic acids and the other using self curing monomers, for long term adhesion to teeth. Drug delivery is going to be revolutionized by biodegradable polymers. Insulin immobilised with oxidized cellulose matrix when injected to rabbits provides sustained release of insulin for over 16 hours.

WHO to study BCG failure

Implications of a trial that has shown that BCG vaccination affords no protection against lung tuberculosis in south India will be discussed by WHO tuberculosis experts. One meeting is scheduled for April and a second for June, 1980. WHO experts emphasise that these results must not be interpreted as an indication that BCG vaccination is useless everywhere.

About 2.6 lakh people living West of Madras were vaccinated either with BCG or a harmless placebo in the experiment which started in 1971. Nearly eight years later, those who received BCG were not immune against tuberculosis. Experts are now studying the possible causes of this failure.

One reason could be the local presence of bacteria similar to the tuberculosis bacilli which interfered with the BCG immunology, according to Dr. K. L. Hitze, Head of the WHO's Tuberculosis and Respiratory Diseases units. Another could be that ethnic groups react to immunisation efforts differently, and what worked in Britain may not be effective in a tropical country like India. Effectiveness of the vaccine ranges from a minimum 89% in one British experiment to zero in the Indian test.

Specialists in immunology, epidemiology and bacteriology from India, USA, USSR, Britain, France, Australia, New Zealand, Denmark and the Netherlands will be meeting first to assess the situation and then recommend whether vaccination policy should be changed.

Antibiotic colitis—New cause, new treatment

A toxin from *Clostridium difficile* has recently been identified as the cause of the severe colitis which can occur following antibiotic administration. The antibiotic most commonly associated with colitis is clindamycin, but it can also occur after lincomycin, ampicillin, the cephalosporins, tetracycline, penicillin G, streptomycin, chloramphenicol, co-trimoxazole and erythromycin. Diarrhoea and fever are the most common symptoms, but abdominal pain and leucocytosis may also occur. Sigmoidoscopy or colonoscopy usually shows yellow-white raised exudative plaques or pseudomembranes. *C. difficile* and its toxin can be isolated from stool specimens with special techniques. Withdrawing the antibiotic is usually adequate, but if this does not stop the diarrhoea, oral vancomycin 500 mg qid should be given for 7-10 days. The effectiveness of vancomycin has been demonstrated in a controlled trial and if patients relapse a second course of treatment should be given. No adverse effects of vancomycin have been reported with its use in colitis. It is a better treatment than oral metronidazole or cholestyramine.

Inpharma, No. **219,** 3 (12 Jan. 80)

Medication for cough

Cough suppression is most harmful in patients with asthma, chronic obstructive pulmonary disease, chronic bronchitis, bronchiectasis and cystic fibrosis. When suppression of a severe cough is required as in lung cancer or in prevention of acute elevation of intrathoracic or intracranial pressure (e. g. some eye disorders or postoperative conditions) morphine or hydromorphone are preferred. Both codeine and dextromethorphan are effective antitussives but dextromethorphan is less likely to cause sedation. The antitussive properties of noscapine are not well established. The effectiveness of guaiphenesin (glyceryl guaiacolate), ammonium chloride, terpin hydrate, iodides, ipecac, camphor, menthol, and chloroform as expectorants has not been established. Increased doses of ammonium chloride can cause acidosis. Iodides and ipecac may be dangerous. Cough remedies may not contain an antitussive drug but may contain sympathomimetic decongestants such as phenylephrine or phenylpropanolamine and an anaesthetic such as benzocaine even though there is no evidence that any of these drugs is effective. If antihistamines such as chlorpheniramine or pyrilamine are present they can cause sedation and may have an unpleasant drying effect on the respiratory mucosa. The alcohol concentration in cough remedies may be as high as 40%. Most acute coughs do not require treatment with drugs. Throat irritation from upper respiratory infection can be relieved with candy drops. Expectoration can be improved with steam or cold mist inhalations.

Inpharma, No. **220,** 2 (19 Jan. 80)

Malaysia: A market with great potential

Malaysia is a very open pharmaceutical market with no pricing controls, registration requirements or restrictions on prescribing. Since virtually all doctors do their own dispensing, the most common form of promotion is bonusing on which doctors depend for a sizeable proportion of their income. Bonusing can be on a one-for-one basis, or even a two-for-one basis depending on the type of product, and price-undercutting through bonusing has made for stiff price competition.

Drugs for use in the government sector are purchased by the Government Medical Store (GMS) which also engages in some drug manufacture for use in government institutions. Supplies are purchased by tender and price competition is fierce with an increasing number of contracts going to generic companies. Generic companies are reported to account for about 50% of the total market.

The ten leading pharmaceutical companies during 1978 are reported to be Glaxo, Sterling-Winthrop and Warner-Lambert/Parke-Davis, all of which operate local manufacturing facilities, followed by Roche, Hoechst-Roussel, Upjohn, Ciba-Geigy, Pfizer, Schering-Plough and ICI/Stuart. The leading local company is the Malayan Pharmaceutical Factory which is reported to rank about 17th in the top 20 companies. According to the local sources, the market is divided between the government sector, which is mainly by tender and accounts for roughly 30% of the total market, and the private sector, which accounts for the remaining 70%.

According to a survey by the Malaysian Pharmaceutical Trade and Manufacturers Association (MPTMA) of its 39 member companies representing some 75% of the market, the ten leading therapeutic categories are as follows:—

Therapeutic class	*1978 Sales $'000s*	*Market share* (%)
Antibiotics	5,890	16
Analgesics and antipyretics	2,110	6
Oral and depot contraceptives	1,810	5
Antitussives	1,740	5
Antihypertensives	1,410	4
Skin protectives	1,380	4
Anthelmintics	1,200	3
Anti-inflammatories and antirheumatics	1,150	3
Tranquillisers	910	3
Anti-asthmatics	700	2

Current health problems include cholera, malaria, dangue, haemorrhagic fever, tuberculosis and leprosy. The principal causes of admission into government hospitals are heart and cardiovascular disease, complications of pregnancy, mental illness, and gastroenteritis.

Future growth of the market is expected to stem primarily from the government sector which is set for rapid expansion under the Third Malaysia Plan (TMP) for the period 1976-80. Expenditure on health and population programmes for the period has been increased by 40% from an original allocation of $ 173 million to a revised allocation of $ 243 million—thus reflecting the government's emphasis on health improvement. The overall aim of the health programme is to expand current health facilities, improve accessibility, particularly in rural areas, and increase numbers of medically qualified personnel. At present 3,058 doctors are registered giving an average population per doctor of 4,347.

Scrip, No. **451,** 13 (5 Jan. 80)

Man-made bacteria

Upjohn has dropped its life-form patent case from US Supreme Court. Its case was combined with General Electric case concerning an oil-spill eating bacteria produced by recombinant DNA technique. Because the Upjohn bacteria (*See* This bulletin Jan. 80, p 9) is a product of fermentation, so it felt that recombinant DNA patent issue would be better contested without its participation.

PMA Newsletter, **21,** 6 (24 Dec. 79)

Premenstrual syndrome

Modest doses of a thiazide diuretic, an anxiolytic, or an analgesic may relieve specific symptoms of the premenstrual syndrome. Likewise rectal or vaginal administration of the progesterone (as cyclogest suppositories) can be given a trial in those women who do not respond well to simpler remedies.

Pharmaceutical J., **223,** 23 (5 Jan. 80)

"Project Sleep" to curb use of hypnotic drugs

Professional and consumer organisations of USA are participating in a programme "Project Sleep" which intends to reduce the prescription of non-barbiturate hypnotic drugs, especially benzodiazepines.

According to the Director of this programme most benzodiazepines have psychoactive metabolities which have a substantially longer duration in the body than the barbiturates, flurazepam metabolites having a plasma half-life of 50 to 100 hours. This leads to accumulation of drug in body when taken on consecutive nights. More than one-third of all drug-related deaths in America involve hypnotic drugs. Keeping all this in view the project has three goals, viz : (1) To improve differential diagnosis, treatment and to promote better prescribing practices for insomnia and sleep disorders; (2) To improve public knowledge about the significance of insomnia and sleep disorders and their treatment; and (3) To identify gaps in the knowledge of insomnia and sleep disorders and about the risks and benefits of taking sleeping medications.

Scrip, No. **450,** 13 (2 Jan. 80)

Abbott to dilute foreign equity

Abbott Laboratories (India) Pvt. Ltd. is issuing 1,350,000 equity shares of Rs. 10 each at a premium of Rs. 6 per share in order to reduce its foreign equity to 40% conforming the new drug policy. Some other companies reducing their foreign equity to this level are CE Fulford, Nicholas of India, Smith Kline & French, Carter Wallace, GW Carnrich Co (Asia) and Anglo-French Drug Co.

Hind Tech-80 exhibition to be held in Baghdad

An exhibition Hind Tech-80 will be organised in Baghdad (Iraq) in March by Engineering Export Promotion Council. The Chemical and Allied Products Exports Promotion Council and Basic Chemicals, Pharmaceuticals and Cosmetics Export Promotion Council are also collaborating in this fair.

The fair is being organised to tap the West Asian market for engineering and other Indian goods. Though the trade with West Asian countries has increased but still it is a small percentage of the market. The reason for this is the lack of knowledge of the industrial progress and capabilities of India in West Asian countries. Technical symposium of mutual interests will also be held during the exhibition period.

Pharmaceutical Companies change names

Biological Evans Ltd., Hyderabad, and Suhrid Geigy Ltd., Baroda, have changed their names respectively to Biological E Ltd. and S G Chemicals and Pharmaceuticals Ltd.

Pharmaceutical exports

Indian Pharmaceutical exports (including medicinal castor oil) during the first eight months of the current year ending March, 1980 amounted to Rs. 41.6 crores, down slightly from Rs. 41.9 crores during the corresponding period of 1978-79, according to estimates published by the Basic Chemicals, Pharmaceuticals and Cosmetics Export Promotion Council. For the full year the export target is Rs. 70 crores.

French drug industry retaliates

From the second half of January, a significant number of pharmaceutical manufacturers in France will either reduce their level of advertising in medical journals or even suspend all medical journal advertising altogether. This is in retaliation against the authorities policies regarding drug prices and limits on advertising and promotional expenses (*See* This bulletin, Dec. 79, p 309). Officially a strike is denied, but this is a simultaneous action by many pharmaceutical manufacturers.

Scrip, No. **456**, 3 (23 Jan. 80)

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REGULATORY NEWS

Caution on use of antibiotics

Inaugurating a national symposium on "Transferable antibiotic resistance in bacteria and its control", Dr V. Ramalingaswami, Director-General, Indian Council of Medical Research emphasised the need of a national antibiotic policy as the indiscriminate use of antibiotics and the resultant drug resistance among germs is on increase. Further he expressed his concern at the unimaginative use of antibiotics as this makes a number of deadly bacteria drug resistant, and also the drugs were being prescribed and administered even in cases where they were least needed.

Drug industry plea to regularise excess production rejected

Government has rejected the drug industry plea to consider growth factor in regularising excess production. The Secretary, Department of Chemicals and Fertilisers told drug industry representatives that such a compound growth, above the licensed capacity, would nullify the whole basis of industrial licensing. However, cases of technological improvements leading to an increased production without the installation of additional machinery could be considered.

The industry's demand for allowing automatic growth of the existing drug units for realisation of growth projection made by the planning commission was also rejected. The projected growth rates were for the whole industry and would be achieved either by a substantial expansion of the existing units or by licensing new units within the parameters of the new drug policy, the secretary said

IDPL suspends bill marketing scheme

Indian Drugs and Pharmaceutical Ltd. (IDPL) has suspended the bill marketing scheme following a freeze on cash-credit limits by the Reserve Bank of India. The scheme, started in early 1979 for the supply of bulk drugs to companies in the organised and small sector on a deferred payment basis, was to be funded by IDPL in collaboration with State Bank of India. But following this freeze, IDPL has found it difficult to manage funds for the scheme.

New guidelines for foreign drug companies

New guidelines have been framed by a high-level committee of the Government of India which went into the working of foreign companies manufacturing bulk drugs not involving high technology and the issue of their equity dilution under the new drug policy.

The panel considered the processes of 207 bulk drugs and found that 93 of these being marketed by 24 foreign companies involved high technology. Of the pharmaceutical companies with a foreign equity exceeding 40%, 20 have been identified as manufacturers of high-technology bulk drugs and only two were found to produce drugs not involving high technology. Of the other two, one has itself gone wholly Indian divesting itself of the entire foreign equity and the other has been asked by the Reserve Bank of India to bring its foreign equity to 40 per cent or less. The two companies (not named) producing no high technology drugs will be required to reduce their foreign equity to 40% while the level of foreign equity for each of the 20 companies producing high technology drugs will be decided in accordance with FERA regulations.

Small-pox vaccination certificate still needed in some countries

WHO has listed the following twenty-three countries which still require small-pox vaccination certificate from travellers although the disease has officially been eliminated. The countries are: Angola, Benin, Brunei, Cameron, Chad, Comoro Islands, Djibouti, Equatorial Guinese, Ivory Coast, Kampuchea, Losetho, Libya, Madagascar, Mali, Nepal, Philippines, Sal Tome and Princippe, Seychelles, Sierra Leone, Sudan, Upper Volta, Zaire and the province of East Timor in Indonesia

Aspirin and Paracetamol combination harmful

Aspirin and paracetamol are useful and effective drugs individually but their combined use without assessing the pharmacological interaction can be harmful. A 5½ years old child when given aspirin and paracetamol alternately every two hours had marked cerebral impairment, diminished neurological function and liver damage. The child recovered within nine days after stopping this treatment.

The features of dual intoxication may or may not represent a composite of the toxicity of either drug alone but the combination should not be prescribed until controlled studies have determined the risk of toxicity.

Pharmaceutical J., **223,** 628 (15 Dec. 79)

DES consumption by pregnant mothers affects male child

A 25 years follow-up study of 308 males born to women who had taken diethylstilboesterol (DES) during pregnancy reveals that they had a significantly higher incidence of epididymal cysts (20.8%) and testicular hypoplasia (8.4%) than 307 controls receiving only placebo. Besides, out of the 26 men with hypoplastic testes in the DES group, 17 (65%) had a history of cryptorchidism as compared to only one out of six in the placebo group. DES exposed men had significantly higher incidence (24 cases) of severely pathological semen, as indicated by Eliasson score greater than 10 on semen analysis, than men (7 cases) exposed to placebo.

Scrip, No. **455,** 13 (19 Jan. 80)

FDA tells SK & F to withdraw Selacryn

US Food and Drug Administration has asked Smith Kline & French to withdraw its uricosuric diuretic product Selacryn (Tienilic acid) from US market following the reports of hypersensitivity reaction in patients which affects the liver.

Scrip, No. **454,** 11 (16 Jan. 80)

Low proinsulin levels recommended for purified insulin

The US Food and Drug Administration's Endocrinologic and Metabolic Drugs Advisory Committee has recommended that all the three species—bovine, porcine, and 'beef-pork'—combination of purified insulin should contain not more than 10 ppm of proinsulin as contaminant.

Scrip, No. **448/449**, 8 (19 Dec. 79)

Reassurance for oral contraceptive users

Dr. William Inman, Principal Medical Officer, Committee on Safety of Medicines, UK, has reassured non-hypertensive women using oral contraceptives of no risk of subarachnoid haemorrhage. A case-control study of women (15 to 44 years) who died from subarachnoid haemorrhage in UK, in 1976, showed small but not statistically significant excessive use of oral contraceptives when compared with their matched controls.

According to the study the use of oral contraceptives may increase the blood pressure and risk of subarachnoid haemorrhage in a few women but hypertension—independent of oral contraceptive use—is itself the most important risk factor in subarachnoid haemorrhage.

Pharmaceutical J., **223,** 628 (15 Dec. 79)

Phenacetin ban move challenged

The Drug Controller's move to ban phenacetin, a popular analgesic and antipyretic agent has been challenged by the drug industry. The move follows a report of the Committee on Review of Medicine, UK, that phenacetin has no place in analgesics, anti-inflammatory or antipyretic therapy and its use over longer periods could damage kidney.

Following this report the Drug Controller consulted some medical experts who gave the opinion that there were other analgesics in the country which could replace phenacetin and yet not have the same renal toxicity. Thus an action to ban the use of phenacetin either alone or in combination with salicylate and other drugs was initiated.

The industry while resenting this has pointed out that some studies have shown that phenacetin given in combination with other analgesics is safer than even aspirin and whatever is applicable in UK and USA need not be inferred to in India. The use pattern of phenacetin in India is different from countries like Canada, UK and USA. The countries with temperate climate have a higher incidence of rheumatic disorders and the patients have to depend upon analgesics and their combinations. In India the most common use of phenacetin is for headache and bodyaches and repeated use of drug is quite infrequent.

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GOVERNMENT OF KARNATAKA DRUGS CONTROL DEPARTMENT

(*Monthly Report: October 1979*)

Details of the Activities

1. *Licences granted:*	Biological drugs	Non-Biological drugs	Homoeopathic	Cosmetics	Poisons
(*a*) For manufacturing	2	4	—	6	—
(*b*) For sale	53	63	1	—	—

2. *Activities*	Manufacturing	Sales Establishment	Hospital	Drugs (Price Control) Order	Poison
(*a*) Inspections	15	346	23	46	—
(*b*) Contraventions detected	—	10	—	—	—
(*c*) Samples of drugs drawn (*d*) Sample of cosmetics drawn	—	29	—	—	—
(*e*) Value of drugs destroyed/confiscated	Rs. 1,400/-				

3. *Administration*	Manufacturing			Drugs sales establishment	Poison
	Drugs	Cosmetics	Homoeopathic		
(*a*) Licences suspended	—	—	—	—	—
(*b*) Licences cancelled	—	—	—	33	—
(*c*) Licences invalidated	—	—	—	59	—
(*d*) Licencees warned	2	—	—	22	—
(*e*) Applications rejected	—	—	—	14	—

(*f*) Prosecutions launched	(*a*) Drugs and Cosmetics Act	(*b*) Drugs (Prices Control) Order
	2	2

4. *Drugs and Magic Remedies (Objectionable Advertisements) Act*

(*a*) Advertisements scrutinised	— 260
(*b*) Prosecutions launched	— Nil
(*c*) Contraventions detected	— 1
(*d*) Warnings issued	— Nil

NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
1.	*Acne preparation*			
	Benzoyl peroxide	Panoxyl	Stiefel	Philippines
2.	*Analgesic*			
	Morphine sulphate	MST-1 Continus	Napp	UK
3.	*Anthelmintic*			
	Mebendazole	Mebendex	Index	Mexico
	Mebendazole	Vermalon	Bequim	Venezuela
4.	*Antiandrogenic/Contraceptive*			
	Cyproterone + ethinyloestradiol	Diane	Schering	Italy
5.	*Antianginal*			
	Nifedipine	Adalat	Bayer	Thailand
6.	*Antianxiety agent*			
	Prazepam	Centrax	Parke-Davis	USA
7.	*Antiarrhythmic*			
	Disopyramide	Rythmodan	Roussel	Thailand
	Mexiletine	Mexitil	Boehringer Ingelheim	W. Germany
	Prajmalium	Neo-Gilurytmal	Kali-Chemie	Philippines
8.	*Antibacterial*			
	Cefaclor	Ceclor	Coli	Italy
	Cefadroxil	Cephamox	Bristol	W. Germany
	Cefradine	Lisacef	Lisapharma	Italy
	Gentamicin + zirconium dioxide	Septopal	Merck	Thailand
	Piromidic acid	Pirogram	Searle	Brazil/ Mexico

Contd.

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
9.	*Antidepressant*			
	Nomifensine	Merival	Hoechst	Thailand
10.	*Antidiarrhoeal*			
	Difenoxin + atropine	Lyspafene	—	Philippines
	Loperamide	Lormide	Medichem	Philippines
11.	*Antifungal*			
	Miconazole	Andergin	Isom	Italy
12.	*Antihistamine*			
	Homochlorcyclizine	Homoclomin	Eisai	Philippines
13.	*Antihyperlipidaemic*			
	Procetofene	Lepanthyl	Green Cross	S. Korea
14.	*Antihypertensive*			
	Indapamide	Fludex	Servier	Denmark
	Indapamide	Natrilix	Servier	Venezuela
15.	*Anti-inflammatory*			
	Acemetacin	Rantudil	Troponwerke	W. Germany
	Diflunisal	Dolobid	Merck Sharpe & Dohme	Italy
	Fenbufen	Lederfen	Lederle	UK
	Indoprofen	Flosin	Montedison	Spain
	Indomethacin	Tannex	Duncan, Flockhart	UK
	Proquazone	Biarison	Sandox	Philippines
16.	*Antineoplastic*			
	Carmustine	BiCNU	Mead Johnson	UK
	Mitomycin C	Mitomycin C	Kyowa Hakko	Philippines
17.	*Antiulcer agent*			
	Pirenzepine	Gastrozepin	Boehringer Ingelheim	Italy
	Pirenzepine	Leblon	De Angeli	Italy
	Pirenzepine	Ulcosan	Dompe	Italy

Contd.

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
18.	*Antiviral*			
	Ribavirin	Virazole	ICN	Philippines
19.	*Bone-calcium regulator*			
	Etidronate disodium	Didronel	Procter & Gamble	New Zealand
20.	*Bronchodilator*			
	Theophylline	Theocontin Continus	Napp	UK
21.	*Hormone*			
	Calcitonin	Calsynar	Armour	New Zealand
22.	*Hypnotic*			
	Flunitrazepam	Rohypnol	Roche	W. Germany
	Triazolam	Halcion	Upjohn	Philippines
23.	*Hypoglycaemic*			
	Buformin	Sindiatil	Bayer	Italy
	Gliquidone	Glurenorm	Boehringer Ingelheim	S. Korea
24.	*Intranasal corticosteroid*			
	Beclomethasone	Becotide Nasale	Glaxo	Italy
25.	*Mucolytic*			
	Bromhexine	Bislan	Yung Shin	Thailand
26.	*Photoprotective*			
	β-Carotin + canthexanthin	Phenoro	Sauter	Switzerland
27.	*Prolactin inhibitor*			
	Bromocriptine	Parlodel	Sandoz	Thailand
28.	*Topical antifungal/corticosteroid*			
	Miconazole + mazipredone	Mycosolon	Gideon Richter	Thailand
29.	*Topical corticosteroid*			
	Amcinonide	Cyclocart	Lederle	USA

Contd.

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
30.	*Topical corticosteroid/anti-infective*			
	Flumethasone pivalate + triclosan	Logamel	Ciba-Geigy	Philippines
31.	*Topical corticosteroid/antimicrobial*			
	Halcinonide + neomycin	Halciderm	Squibb	Italy
32.	*Vasodilator*			
	Isoxsuprine	Suprilent	Duphar	Switzerland
	Vincamine	Oxygeron	Will Pharma	Philippines

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NATIONAL INSTITUTE OF OCEANOGRAPHY, GOA

A PROFILE

National Institute of Oceanography, Dona Paula, Goa, was established in 1966 with an objective to study the physical, chemical, biological and geological aspects of the seas around India. It has also been recognised as a National centre for the storage of oceanographic data and to act as the principal centre for fabrication of oceanographic instruments and consultancy in marine engineering problems.

NIO's research activities are multidisciplinary such as physical oceanography, chemical oceanography, biological oceanography, geological oceanography, oceanographic instrumentation and ocean engineering. Three regional centres—at Cochin, Bombay and Waltair—also contribute substantially to the research activities of the institute. Gaveshani, a research ship of the institute, is helping in the fulfilment of the objectives of the research.

The projects currently going on in the institute are :—

Physical oceanography division:

Problems relating ocean-atmosphere interaction, physical processes in the Indian ocean, land-sea interaction and coastal zone management are being investigated.

Chemical oceanography division:

The division is working on the chemistry of sea water and of marine organisms and sediments and its application to the raw materials, productivity and marine pollution. Investigations on important nutrients, new drugs and drug intermediates from marine plants and animals and chemical aspects of marine pollution and its effects on marine life are also being studied.

Biological oceanography division:

The biological potential of Mandovi-Zuari estuaries and backwater of Cochin has been studied. Availability of living matter in the seas around India and in estuaries, backwaters, and mangrove swamps are the other aspects on which research is being done.

Similarly, geological oceanography division is engaged in studying the geology of the Western Continental Margin of India with special reference to its numeral and oil potential.

Drugs from sea: Currently a project in collaboration with Central Drug Research Institute, Lucknow, has been undertaken to obtain drugs from sea and some useful work has been reported. A large number of extracts prepared from marine plants and animals have been screened for antiviral, antibacterial, antifungal, antiprotozoal, antifertility activities and effects on CNS, CVS and isolated tissues studied. Five species of corals and two species of seaweeds have shown 100% antifertility activity. This could possibly lead to the development of new antifertility agents.

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DRUGS & PHARMACEUTICALS
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DRUG INDUSTRY NEWS

Project to extract HCG from urine

A private sector project for the extraction of a protein hormone known as Human Chorionic Gonadotrophin (HCG) from the urine of pregnant woman has been taken up for the first time in India. The hormone is a precursor of a drug used to treat infertility in women caused by non-ovulation, menstrual disturbances and also for treating sterility in men. The presence of this hormone in urine can also indicate pregnancy at a very early stage. The West Bengal government has directed hospitals and health centres in and around Calcutta to extend all possible help for this project in the collection of urine of pregnant women.

The HCG protects the foetus in a pregnant woman and helps in its growth. It is secreted into blood and the excess goes out through urine where it can be detected within 48 hours of conception. The secretion continues during the entire child-bearing period, but it reaches its peak in the first four months of pregnancy.

The project is suffering from a few constraints such as many families do not like to be associated with the project and some do not want an early disclosure of pregnancy. The disclosure made at a very late stage makes the project non-viable because by that time the secretion of HCG is considerably low. Also in poor and lower middle class families storage of urine is a problem.

Family planning methods in 80's

During 1980's, a major development that can be foreseen in the field of health and family planning will be the availability of objective and precise estimates of relative risks of diseases such as tumours of breast, uterus and liver, thromboembolic complications and increase in blood pressure in different population groups, the Director General, Indian Council of Medical Research and President Indian National Science Academy, Prof. V. Ramalingaswamy, stated while delivering the presidential address of the academy.

He also expected more data on alterations in carbohydrate, fat, mineral and vitamin metabolism, lactation and steroids transfer to the infant through mother's milk, which occur following long-term use of oral contraceptives.

This decade could see the introduction of a second generation of medicated intrauterine devices (IUD) which will reduce menstrual blood loss, intermenstrual bleeding, ectopic pregnancies, pains and expulsions. Development of a special post-placental device which can be inserted immediately after the delivery of the placenta requires to be taken up on a priority basis. A revival of interest in agents derived from indigenous and traditional systems of medicine which act orally as uterotonic agents and thus as menses inducers is also visible, he said.

These days the contraceptive technology is female oriented, so suitable male contraceptive methods need development. Also, emphasis on research should shift from compounds that interfere with sperm maturation to compounds which inhibit spermatogenesis.

WHO Chief: India can lead Third World in health care

Dr. H. Mahler, Director-General of World Health Organisation, has said that India has the necessary background and infrastructure to develop new technology in the field of health delivery and disease control and thus can assume the leadership of third world countries in fulfilling the Alma Ata declaration of "Health for all by 2000 AD".

Indian and other signatories of the Asian Charter for Health have committed themselves politically to make health care an important component of economic development and work out national policy to achieve the goal of health for all by 1990.

According to Dr. Mahler, efforts should be made to have drinking water facility available to all villages within the next 20 years. Sanitation is another point which he stressed in rural health care.

Medicinal plants export potential

While inaugurating a seminar on "Export potential of medicinal plants" organised by the Basic Chemicals, Pharmaceuticals and Cosmetics Exports Promotion Council, Mr. K. V. Ramanathan, Secretary, Union Ministry of Petroleum, Chemicals, and Fertilizers emphasised the need to organise export of medicinal plants in an orderly fashion. This will give a boost to medicinal plant farming and will help Indian exporters to enter into long-term export arrangements with foreign buyers. The exporters should go in for the export of finished herbal products and other value-added items. Also the export should be diversified to more and more countries rather than restricting it to a few coun- tries of Europe and USA.

Hyderabad drug unit achieves breakthrough

Uniloids of Hyderabad has developed the technology for production of sulphamethoxazole, trimethoprim and 3,4,5,-trimethoxy benzaldehyde, the latter used for curing urinary infection. A British firm of consultants, British Medical Associates, has asked for the technical know-how of this aldehyde. An important intermediate used for the production of 3,4,5-trimethoxy benzaldehyde is gallic acid which is an import item. But the company has successfully extracted gallic acid from myrobalan

(*Terminalia chebula* Retz.) and is setting up a plant near Hyderabad for its commercial production and the end-product.

Some multi-nationals have shown interest in another product developed by this company—the drug tinidazole, used in amoebiasis. The company is also going in a big way for the production of intermediates for Cimetidine—a potent drug for ulcers; it will make some of the intermediates and then evolve the basic drug out of them.

Rhone-Poulenc to open liaison bureau in India

Rhone-Poulenc, the French drug multinational, which achieved a sale of $ 37.1 million in India in 1979 is going to open its liaison bureau in India from 1 June, 1980. The company sold, through an agent, chloroquin to local drug manufacturer, drug products (through its M & B subsidiary), agrochemicals, plant protection products and textiles. The decision to open the bureau is consequential to French President's recent visit to India when it was decided to increase co-operation and trade between the two countries.

ICMR plans new strategies in research and disease control

The Indian Council of Medical Research (ICMR) has planned some new strategies for research and control of diseases in this decade. Control of filariasis, communicable diseases, malnutrition, population growth and health delivery systems will be some of the projects which will be taken up for more exhaustive studies. The Council will also continue supporting the basic research including genetic engineering. An Indo-American workshop on genetic engineering has also been planned which will give practical demonstrations of techniques used in genetic engineering. It is also planned to strengthen the medical surveillance system for diseases like kala-azar and encephalitis so that they do not recur.

Development of vaccines against malaria and leprosy is under way. Antigen from the cultured malaria parasite has been obtained and this will help in development of a vaccine. In case of polio, the killed polio vaccine is undergoing trials as this may be more effective than currently used oral polio vaccine.

President exhorts scientists to develop alternative energy sources

President N. Sanjiva Reddy called upon Indian scientists to concentrate more on finding alternate sources of energy, while inaugurating the 67th Indian Science Congress at Calcutta. Vital sectors of economy are being affected by a steep rise in oil prices. Coal being a non-renewable fossil source can not be used as a long range fuel. Nuclear power provided an alternative but the progress in this field was governed by socio-economic constraints. President commended the theme of the Science Congress, "Energy strategies for the future".

Many interesting studies were reported in the Science Congress such as the reversal of plant sex by which seeds yield only female plants. This is brought about by application of growth regulators, such as gibberellic acid. A new method for the study of leukaemia, using proton-magnetic resonance, infra-red, spectrophotometric and spectro-fluorometric techniques was also presented. It consists of examining the blood samples before and after dehydration and noticing the changes in the spectral shape of the optical absorption lines in case of leukaemic and non-leukaemic patients. An abrupt change in the value of absorption intensity ratio occurred indicating, possibly, chronic myelocytic leukaemia. In another paper, a doctor of Chittaranjan Cancer Hospital cautioned against radiation therapy for treating cancer. The therapy can make the cancer malignant and in support of this many cases were cited.

Essential drugs shortage feared

Drug industry sources are predicting a shortage of many essential drug formulations such as those used in tuberculosis, malaria and hypertension if certain corrective measures are not undertaken immediately. Lack of sufficient returns to the manufacturer and shortages of raw materials are the two major causes of this anticipated drug shortage.

According to the industry sources the production of category I and II drugs (categorised as essential by government) at the new mark-up of 40 and 55 per cent would result in a loss of about 20 per cent on every rupee worth of drug sale. But the Government maintains that losses thus accruing would be compensated by additonal margins allowed for category III and IV formulations. But the drug units contest this as all units may not be manufacturing category III and IV drugs or their products of these categories may not have good sales.

The new Drug Price Control Order 1979 does not give an automatic revision of prices, whenever raw materials become costlier. Drug Units have to approach Bureau of Industrial Costs and Prices for offsetting cost escalation by increasing drug prices. As the prices of raw materials etc. have gone up between 30 and 140 per cent, the industry has to bear the brunt in the form of reduced profitability.

Export of basic drugs declines

The basic drugs export which was a record Rs. 11.47 crores for 1978-79 has fallen so much that for the first 10 months of 1979-80 it is only Rs. 6.45 crores. The export in the corresponding period of the last year was Rs. 7.81 crores.

Of about 15 items of basic drugs which India exports, two, namely beta ionone and papain, have shown the maximum downfall. Beta ionone export amounted to Rs. 2.68 crores last year during this period, whereas it is only Rs. 88 lakhs this year. Lesser offtake by USSR is the main reason for it. Similarly papain has so far been able to achieve sales worth only Rs. 71 lakhs, whereas, last year it was Rs. 1.45 crores.

A slight fall in the export of drug formulations is also visible in the current year. The export of formulations and allied items declined to Rs. 16.97 crores in the April-January period of the current financial year while the corresponding figure in the 10 month period of the previous year was Rs. 17.1 crores.

ICMR recommends copper gadget for birth control

Indian Council of Medical Research has suggested inclusion of "T" shaped copper gadget in the national family welfare programme. The trials of the device have shown that it can be effectively used by women. The gadget works by gradually releasing small amounts of copper that prevents the ovum's settling in the womb and growing into a foetus. The Council experts say that the gadget, once implanted, is effective for at least six years. The Council's recommendation is under the consideration of the Government.

Hindustan Antibiotics Ltd. to set up drug plant in Goa

HAL proposes to set up a joint sector drug formulation unit in Goa in collaboration with the State Government. This would be the third such unit to be set up by the HAL. Work for one at Nagpur has already been started in collaboration with the State Industries and Investment Corporation of Maharashtra. Another such plant is to be set up near Bangalore in collaboration with the Karnataka Government.

As a part of its expansion programme, HAL is raising its capacity for manufacture of penicillin and streptomycin. Under its long range plan, HAL has submitted to the Government a prefeasibility report for a Beta-Lactum Antibiotic complex also.

New drug unit launched in Calcutta

GNK Drugs Company (P) Ltd., Calcutta, a new drug unit, was inaugurated on February 10 by Mr. Janardan Das, Drugs Controller, West Bengal. The unit has been started by a group of young entrepreneurs, working in India and abroad and has plans to introduce several unique drug formulations. It has got licence for 46 drugs but to start with it will market only nine drugs.

The company plans to market an unique combination drug of Ampicillin and Probenecid which it claims to be a first combination of its kind in Asia and Europe. The company will have a R & D department also. All kinds of manufacturing set-ups i.e. tablet, liquid, capsule and injection or ointment shall also be provided.

Mexico seeks drugs know-how from India

A special study of Mexico and Panama conducted by Indian Institute of Foreign Trade has revealed Mexico's interest in acquiring Indian know-how in the development of raw materials for a wide range of drugs especially sulfa drugs, vitamin C, vitamin B_1, riboflavin, barbiturates, steroids and amphotericin.

Mexican authorities have agreed to assist Indian entrepreneurs in identiying suitable partners in that country. The study states that Mexican pharmaceutical industry is not well developed although significant progress has been made in items like antibiotics, vaccines and blood derivatives. There is therefore, a potential of exporting a good number of drugs or drug intermediates, till the indigenous capacities are developed in that country. The products so identified are paracetamol, dextropropoxyphene, glybenclamide, diazepam, nicotinamide, indomethacin, phenacetin, hydrochlorothiazide, reserpine, nicotinic acid, tolbutamide, psoraline, xanthotoxin, and kanamycin. An association of 25 pharmaceutical companies of Mexico—MAPRIMEX—has also shown keen interest in importing a number of products from India.

Iran to get Indian Drugs

Iran, which had made a special request for certain essential drugs, will get drugs worth Rs. 1 crore from India. The drugs being sent are as follows: ampicillin injection 500mg vial, chloramphenicol sodium succinate injection 1g, furosemide injection, insulin, gentamicin injection 80 mg, calcium gluconate injection 10%, amoxicillin 250 mg, amoxicillin syrup for oral suspension 125 mg and diazepam injection 10 mg/2 ml.

Indian drugs for USSR

Sandoz (India) Ltd. has signed a contract with Medexport of Russia to export Intestopan tablets worth Rs. 1 crore to Russia during the first quarter of 1980. Sandoz India is the major exporter to Russia and every year its exports amount to about Rs. 2 crores.

During this period, Ciba-Geigy of India will also be supplying to USSR about 2 lakh packets of adelphan-esidrex, which is used as an antihypertensive drug.

Largest homoeopathic hospital for Delhi

The Delhi College of Homoeopathy has got the biggest homoeopathic hospital in the country with the recent increase in its bed strength from 50 to 100. The hospital provides treatment for asthma, skin diseases, allergic conditions and gynaecological problems. In accordance with the recommendations of the Central Homoeopathic Council, the 100 bed hospital would have 60 medical beds including those for women and children, 20 beds for surgical cases and 20 for gynaecology.

Anti-leprosy vaccine developed

An anti-leprosy vaccine from dead leprosy germs, taken from two years old armadillos, has been developed at the National Institute for Medical Research, London. Experts of the World Health Organisation—the sponsoring agency for this work—will now decide about the full scale trials of the vaccine. The vaccine, given only once to children, will overcome the problem of repetitive drug injection. This would eventually lead to total eradication of the disease like small pox.

A WHO experts meeting in Geneva discussed in what form the vaccine trial should be undertaken and where and when it should be staged, as the vaccine has already been tested successfully in the laboratory and on a small number of volunteers. In the anticipated trials starting sometimes next year, a large number of people shall be involved, and it will take upto ten years to establish the vaccine's effectiveness (*See* this bulletin, Vol. **2,** No. 12, p 229).

Contraceptive pill from Hashish

Hashish, the intoxicating resin extract of Indian hemp, will soon become a source of a new contraceptive pill for women. Some Israeli researchers have found that small amounts of hashish can prevent ovulation in rats for 24 hours and larger amounts can prevent ovulation in rhesus monkeys for sixty days.

The idea to produce contraceptive pill developed after observing low fertility in women who had smoked hashish in great quantity. Researchers are now going in for a synthetic version of the contraceptive substance so as to avoid the side effects while having direct effect on ovulation.

Neem useful in mouth cancer

According to Dr. David Barnes, Chief of Oral Health Programme of World Health Organisation, proper use of neem (*Azadirachta indica* A. Juss.) can restrict mouth cancer. He advocated the use of neem and advised chewing of a neem stick daily to keep mouth clean.

The incidence of mouth cancer is highest in India, a 35 to 40 per cent, whereas, North American and European countries have only 3 to 5 per cent. Reverse smoking, pipe smoking, tobacco and betelnut chewing are the main causes of mouth cancer in India.

GOT enzyme levels in brain strokes

Cerebral thrombosis (blood coagulation), cerebral haemorrhage (bleeding), cerebral embolism (obstruction), and puerperal venous sinus thrombosis are the four types of brain strokes identified by a team of doctors of Lady Hardinge Medical College, New Delhi. This will not only help in identifying the type of the stroke but would also help in predicting the survival prospects of stroke victims on the basis of the level of an enzyme called glutamic oxaloacetic transaminase (GOT) in the blood serum and cerebrospinal fluid. The Delhi team observed that the GOT level starts rising on the first day of the stroke, reaches its peak on the fifth day and starts declining thereafter but remains high up to the 10th day of the stroke.

Caffeine causes birth defects

Preliminary results of a US Government study on the harmful effects of caffeine, the stimulant in coffee, tea, chocolate etc., have shown that it causes birth defects in the offspring of rats. The quantity of caffeine given to the rats was slightly more than the normal level of human consumption but according to the study the difference was not much.

Negative brain wave discovered

Drs. Steven A. Hillyard and Marte Kutas of the University of California, San Diego, have found a negative brain wave which a person emits when something does not make any sense to him.

The neuroscientists who tested over 100 persons over a period of 18 months found that the negative wave shows up only when the subject does a "mental somersault", as with an inappropriate or incongruous thought. It also appears when a sentence ends with a thought different from that with which it starts. They named the wave as N-400; N for negative and it peaks 400 milliseconds after stimulus, and it is different from the continuous rhythms of the brain as seen in electroencephalograms.

A new asthma drug on the way

A study by the scientists of Harvard University and Karolinska Institute, Sweden, has resulted in the synthesis of a potent chemical known to be the cause of asthma and severe allergic reactions.

The chemical, named Slow Reacting Substance (SRS) or leukotrience C, is present in very minute amounts in body, i.e. about one trillionth of a gram in tissues. It is a powerful muscle contractant which constricts the air passage to lungs and is released when the antibodies respond to foreign substances like house dust, plant products, insect venoms, etc. a person is allergic to. According to the study the effects of SRS are like histamine, which causes muscles to contract suddenly and then return to normal. SRS's effects start slowly, but last long. Antihistamines have been found to be of not much help in countering the effects of SRS. But now anti-SRS drugs are under development which one day would combat asthma and anaphylaxis.

Strange infants' illness worries paediatricians

Kawasaki disease, formerly known as mucocutaneous lymph node syndrome, is a puzzling new illness that is occurring in large numbers in US and many other countries Kawasaki disease was first reported by Dr. Tomisaku Kawasaki of Tokyo, Japan. It initially appears to be a scarlet fever and is characterized by prolonged fever, inflamed eyes, sore throat and a body rash. Between one to two per cent of the children who get this disease develop some kind of heast trouble leading to death within six months.

According to Dr. Bell of the US National Centre for Disease Control's Bureau of Epidemiology, the biggest impediment in the cure of this disease is its unknown etiology. It is not known whether the disease is contagious, or is caused by a virus or a bacterium.

Mosquito control: new methods

A non-toxic plant extract which curbs the mosquito population has been discovered by Dr. O. K. Kaul of the Regional Research Laboratory, Jammu. The sterilising principle has been extracted from *Aristolochia bracteata* and is reported to be so effective that mosquitoes get sterilised simply on exposure to the vapours of plant product. As the female mosquitoes mate only once, if the mating takes place between sterilised mosquitoes the eggs fail to hatch. So a large number of laboratory sterilised mosquitoes when released in the field, on mating with wild females, will produce no offspring and the mosquito population will gradually dwindle.

The extract being non-toxic is safely applicable in fields or barns. It is so safe that it is being used in indigenous medicine for the treatment of minor eye ailments.

Gene copying structure in the cell nucleus discovered

A team from the medical school of Johns Hopkins University is believed to have located a structure in the cell nucleus called "nuclear matrix" on which cell genes are copied. The finding could throw light on the process of cell division and reproduction, the details of which are not properly understood.

Dr. Donald Coffey, professor of pharmacology, oncology and urology at the University and leader of the experimental team, has said that the most common theory was that the copying apparatus moves along the long DNA molecule like a pulley along a fixed line. But their experiments indicate that the replicating machinery is fixed to the nucleus matrix. Johns Hopkins scientists believe the DNA is reeled through the fixed replicating machinery like a clothesline through a fixed pulley.

It appears the DNA is attached to the matrix as a continuous series of small loops. Each nucleus contains many thousands of these loops and replicating sites and this configuration allows the cell to duplicate its DNA in an orderly manner.

Vitamin C minimum daily intake

There is no common agreement on the minimum daily intake of Vitamin C, but it has been recognised as essential for man. Because it can not be synthesised or stored in any significant amount within the body, the pharmacopoeias of various countries have recommended its minimum daily intake. The USSR pharmacopoeia has recorded the highest daily intake, whereas UK, Australia, Canada and Norway have recommended lower daily intake, as the following Table shows:

Country	Vitamin C (mg)
Australia	30
Canada	30
Norway	30
Switzerland	75
UK	30
USA	70
USSR	100
W. Germany	75

Russians have probably recommended higher dose because of their low consumption of fruits particularly citrus and green vegetables during winter. On similar lines India should also go for a higher Vitamin C intake because its per capita consumption of fruits and vegetables is perhaps among the lowest in the world.

Peptides in urine and mental illness

A group of Norwegian doctors have found that urine sample of psychiatric patient has an excess of peptides. These peptides when given to some animals induced the conditions of psychiatric illnesses which lead to mania, depression or schizophrenia. The exact cause of the generation of these peptides has not yet been established but possibility is that they may be present in such individuals since birth or may be induced in healthy people by environmental factors.

Pharmaceuticals to be produced in space

The US National Aeronautics and Space Administration under an agreement with McDonnell Douglas Astronautics Company and an unnamed pharmaceutical firm will develop a new technique of continuous flow electrophoresis for materials processing in space. This is the first joint venture of NASA to commercialize the space. According to NASA the process has a high probability of producing substances useful in the diagnosis, treatment or prevention of human or animal diseases. These substances are currently not being produced in sufficient quantities or purity in ground based facilities. McDonnell Douglas will act as the space manufacturer of the project, whereas, the drug firm will further develop the product on earth.

PMA News letter, **22**, 7 (4 Feb. 80)

Antiviral drug for Herpes

Dr. V. S. Gupta and colleagues working at the University of Saskatchewan, Canada, have developed an antiviral drug which gives very promising results against Herpes I and II infections. This drug is having a much reduced toxicity as compared to other products currently in market.

Scrip, No. **458,** 10 (30 Jan. 80)

Gonorrhoea treatment

According to a recently published WHO newsletter, treatment of gonorrhoea should be on the basis of continuous evaluation of gonococcal sensitivity to antibiotics. Gonococci are still sensitive to antibiotics but some penicillin resistant strains have appeared. Antibiotics treatment has led to the selection of gonococcal strains with a high resistance to antibiotics, necessitating strong doses thus raising the cost of treatment. The report says that hopes of an early development of a gonorrhoea vaccine are in sight.

Pharmaceutical J., **224,** 110 (26 Jan. 80)

Human rotavirus grown through cell culture

A cell culture technique has been successfully used by the scientists of the US National Institute of Allergy and Infectious Diseases in growing human rotavirus in significant quantity. This culture will give a boost to research in understanding the genetic structure of the virus and will possibly lead to the development of an attenuated virus for use as a vaccine to prevent diarrhoea in small children.

Scrip, No. **460,** 11 (6 Feb. 80)

Streptococcus faecium to treat diarrhoea

Diarrhoea and allied symptoms were completely cured and the patient became perfectly normal when they were given 3-4 capsules daily for 6-10 days of *Streptococcus faecium* strain SF68 (containing 75 million lyophilised organisms per capsule). It is a completely harmless commensal of the human and animal digestive tract and regenerates *in vitro* in about 19 minutes and has a high inhibitory effect *in vitro* on the growth of *E. coli* by an unknown mechanism. Minimum inhibitory concentration of *S. faecium* ranges 4-8 μg/ml for ampicillin and chloramphenicol and up to 500 μg/ml for co-trimoxazole. Diarrhoea and abdominal pain stopped within 1-3 days, faecal pH dropped from about 8 to 7 in 2-3 days and Gram-negative Gram-positive ratio of the intestinal flora changed from an extreme of 95: 5 to 60: 40 (normal) in 2-4 days. The responsible pathogen *E. coli* disappeared without any side effect and no abnormal blood chemistry was observed.

Inpharma, No. **223**, 13 (9 Feb. 80)

Hypoxic sensitiser for cancer treatment

Misonidazole and metronidazole are two "hypoxic sensitiser" drugs which are being tested for the treatment of solid tumours, in conjunction with radiotherapy, as they induce sensitivity to radiation in tumour cells. The advanced tumours often have a poor blood supply and may have areas of hypoxic cells which are insensitive to radiation. It is possible that these radioresistant cells may survive treatment and then become re-oxygenated and lead to a recurrence of the disease.

Studies carried out using metronidazole and misonidazole have shown the latter to be more effective but having dose-limiting neurotoxicity. U. K. Medical Research Council's trial of these drugs involves patients with brain tumours, advanced oral and pharyngeal cancers or advanced cancer of the uterine cervix. In addition to radiosensitizing properties, these drugs have been found to have a selective toxicity to hypoxic cells, thus having a possible role in chemotherapy of solid tumours.

All the trials are still in an early stage and it may take years for results to come, but the use of hypoxic sensitisers has been accepted as a promising field in cancer treatment.

Pharmaceutical J., **224,** 137 (2 Feb. 80)

US Pharmaceutical Association pleads for life-form patent

The US Pharmaceutical Manufacturers Association has appealed to US Supreme Court to grant a patent on a microorganism developed by Dr. Ananda Chakrabarty of General Electric Company through recombinant DNA techniques. The Association has pleaded that genetic engineering research and development is precisely the type of technological innovation which the patent system intends to promote. So far the Patent Office has refused to grant the patent (*See* this bulletin Vol. 3, No. 1, p 9 & Vol. 3, No. 2, p 42).

Scrip, No. **462,** 7 (13 Feb. 80)

Cephalosporins the largest selling drugs in Japan

The three largest selling prescription drugs in Japan in 1978 were all cephalosporins. Leading the drug sales was Cefamezin (cephazolin sodium, monthly sale Y 3300 m), Keflex (Cephalexin, Y 2500m) and Keflin (Cephaloridine, Y 2450m). Two other brand names of cephalexin namely Larixin and Syncle were in eighth and ninth places. Combined sales of the 10 biggest selling branded drugs accounted for more than 12 per cent of production of prescription drugs.

Pharmaceutical J., **224,** 95 (26 Jan. 80)

UNIDO assistance to pharmaceutical industry

UNIDO has prepared a plan to help the third world countries in the development of their pharmaceutical industries. UNIDO and WHO have reached an agreement to ensure effective co-operation in the implementation of this programme.

The plan reveals that in many developing countries the per capita consumption of medicines is just one dollar compared to about 50 dollars in the developed countries. Out of 88 developing countries, whereas 45 have only a pharmaceutical formulation industry based on imported raw materials, the other 43 do not have even this much facility. For about 80% of rural population of these developing countries the only form of medication is traditional herbal medicine and faith healers.

The plan envisages to develop the capabilities of developing countries by setting up regional centres in them. One such centre in India will be at Hyderabad. India is a country where many serious efforts have been made in the past and are still being made to develop the pharmaceutical industry. The UN assistance to the project is about 1.7 million dollars and the centres will be equipped with pilot plant facility and infrastructure for the development of national and sub-regional industry.

Useless drugs in thousands: WHO report

A recent report of the World Health Organisation has questioned the production of thousands of drugs when mankind needs only about 200 drugs to cure itself of most of its ailments. It has urged the countries to make a list of essential drugs so that unwanted drugs, now thrust upon them by pharmaceutical companies, could be kept out of circulation This list should be periodically revised and adapted to the special needs of health.

The pharmaceutical preparations sold in the world market number between 950 and 35,000. The lowest figures are for the countries with controlled economies. If the unwanted drugs are kept out, this would result in a lot of saving. Presently about 100 companies are supplying 90% of drugs used all over the world.

Check against diarrhoeal diseases urged

The World Health Organisation has urged the developing countries to take up action against the spread up of diarrhoeal diseases. It has recommended the use of Oral Rehydration Solution (ORS)—a mixture of table salt, baking powder, potassium chloride and sugar—in combating these diseases. India is among more than 60 countries who are likely to make the control of diarrhoeal diseases a part of the primary health care programme. The effectiveness of ORS had been proved to India when an outbreak of diarrhoeal diseases was successfully controlled among Bangladeshi refugees in 1971.

Nearly 60 lakhs, mainly children, die every year because of a variety of acute diarrhoeal diseases, including cholera. Death occurs most often when body loses life sustaining water and salts leading to dehydration. ORS replaces these losses orally, much easier than intravenous treatment and also much cheaper compared to intravenous fluids.

A WHO expert group has recommended that ORS should be supplemented by better feeding and hygienic practices. The experts have proposed that by 1983, atleast 25 per cent children in developing countries should have an easy access to ORS therapy. Field trials in six countries have shown that children who are given ORS and properly fed gain weight.

Drug Industry wants price hike

The Organisation of Pharmaceutical Producers of India (OPPI), All India Drug Manufacturer's Organisation (AIDMO) and the Pharmaceutical and Allied Manufacturers and Distributors Association Ltd. (PAMDAL) have jointly represented to Union Petroleum and Chemicals Ministry for a hike in prices of bulk drugs because of increases in input costs. The representation points out that unless the Drug Price Control is withdrawn, the industry can not function at a profitable level and this will soon lead to many units becoming sick.

The industry in support of its demand for price hike has quoted the rise in price of many commodities. They include all petroleum goods like naphtha whose price has risen by over 140 per cent. Price of packaging material has also shot upwards. Scarcity of diesel oil and consequential price rise is also a fact. Increasing wages and restrictions on credits by banks are also playing havoc, the industry sources say. Industry for its survival has appealed to Government to allow them a price hike in order to compensate the spiralling rise in costs.

Discovery of a new nerve claimed

Dr. Masaharu Horiguchi of the Tohoku University Medical College, Japan, has claimed the discovery of a new nerve near deltoid shoulder muscle. The new nerve is reported to be a branch of scapular nerve that controls the movement of the shoulder muscle.

Gout remedy useful for heart patients

Sulfinpyrazone marketed as anturmine, which has been used in the successful treatment of gout, has been found to be a preventive medicine for heart patients. Administered to a patient during the convalescing period after the heart attack it cuts the chances of sudden death by more than half.

Leukemia cells grown in test tube

Scientists of the Emory University, USA, have developed a new method to grow leukemia cells in test tubes by modifying earlier techniques, used to produce normal blood cells in the laboratory. The technique will enable scientists to grow leukemia cells from leukemic children and test new drugs on cells themselves rather than on patients The technique requires a mixture of nutrients to promote the growth of cells drawn from bone marrow. At Emory, the doctors are in quest of drugs or their combinations to destroy the diseased cells but sparing the healthy cells.

No drug trials at human risk

Indian drug control authorities have denied the reports that Indians are being used as guineapigs for trials of new drugs by foreign drug companies. According to the authorities no drug is allowed for clinical trials unless a satisfactory proof of its having been adequately tested in animals and also in human beings is submitted. The regulatory provisions regarding both the imports and manufacture of new drugs have been made so stringent that it is not possible for any drug manufacturer, Indian or foreign, to expose the people to unnecessary risks. Clinical trials are conducted only by the Clinical Pharmacologists approved by the Drugs Controller. Government's policy of not allowing any trials here, in respect of foreign drugs unless adequate clinical data on trials carried out abroad were available, has led to the generation of adequate data for Indian patients without exposing them to unnecessary risk.

Pfizer denies move to dispose of holding

Pfizer India has denied any move on its part to sell the holding of Pfizer Corporation of Panama to an Indian industrialist, either Apeejay or Modi group. The Pfizer Panama holds 75 per cent shares of the Pfizer India. Mr. S. V. Pillai, Managing Director of the Indian company says that there is absolutely no truth in the sell out news but the company is proposing to go in for the manufacture of some new products. They include drugs for worm infestations, gastrointestinal infections, hypertension and psychotherapeutic problems.

It is also planned to introduce some important Pfizer discoveries in India and for that clinical research programmes are already underway. This is keeping in view of the need to dilute foreign equity from 75 to 60 per cent. The dilution is likely to be achieved by rights issue to the existing shareholders, employees of the company and to some financial institutions.

Pure HCl plant commissioned

A plant to produce 250 MT per day of mercury free pure hydrochloric acid was commissioned on 1 February for Travancore-Cochin Chemicals Ltd., the largest state-owned undertaking in Kerala. The plant based on modern technology will produce high grade acid such as to be used in food industry. The plant is installed as an adjunct to the caustic soda plant.

Bulk of the produce will go to Kerala Chemicals and Proteins Ltd., for the production of Ossein—an intermediate for making gelatin. Gelatin, in turn, is extensively used in pharmaceutical industry and also in chocolate and other sweets manufacture.

Protein products India Ltd. sales go down

Protein Products of India Ltd. has achieved a sales turnover of Rs. 2.65 crore for the year ending September 1979, a drop of 5% on Rs. 2.79 crore for the previous year. The total accumulated losses of the company so far are Rs 1.29 crores.

British aid for Foot and Mouth disease vaccine

A plant to manufacture vaccine for the foot and mouth disease will be set up at Hyderabad with Rs. 12.4 crores worth of British aid.

The plant to be owned by Indian Dairy Development Corporation will get know-how from Wellcome Foundation of Britain and will produce 25 million doses of vaccine per year. Production, expected to meet 15% of the total demand, will commence by March 1983.

Award to commemorate Wellcome Foundation Centenary

To commemorate its centenary this year, the Wellcome Foundation (parent company of Burroughs-Wellcome India Ltd.) together with Royal Society, UK has announced a biennial award for original contribution to medicine and veterinary sciences, published within a 10 year period from the date of the award.

The award will comprise a gold medal and £ 2,500 and will be known as Royal Society Wellcome Foundation Prize and Lecture.

"Bench-top mini spray-dryer"

A new equipment for spray-drying solutions, emulsions and dispersion will enable small samples of substances to be spray-dried on an experimental scale. Digital displays for inlet and outlet temperatures and input connections for a pen recorder have also been provided so as to facilitate accurate control and allowing a permanent record of each experiment. Further information can be had from: Orme Scientific Ltd., P. O. Box 3, Stakehill Industrial Estate, Middleton, Manchester M24 2RH, England.

Pharmaceutical J., **224**, 82 (19 Jan. 80)

4th International Chemistry Show

The 4th International Chemistry show will be held in Bucharest-Romania from 7 to 15 May, 1980. Display at the show will not only cover machinery and equipment for chemical industry but also fine chemicals and other resultant products. Following are the products of display:

Cosmetics, perfumery products and soaps,

Chemicals, chloro-sodium products, reagents, lacquers and paints,

Chemical fertilizers, insecticides and fungicides,

Lube oils and paraffin,

Machinery and equipment for the chemical plastics and rubber industry, and licences, patents, know-how and specialist literature,

Pharmaceuticals and dental materials, photographic chemicals, packings for chemicals,

Raw materials for chemical, petrochemical and pharmaceutical industries.

Further information can be had from: The Fair and Exhibition Co., Exhibition Complex, 1, Piata Scinteii, Bucharest, Romania.

Use of Depo-Provera in nursing mothers

Dr. Gerard Vaughan, British Minister of Health told British Parliament that though steroid hormones used as contraceptives do enter the breast milk and could affect its protein, fat and calcium contents, the use of injectable contraceptive Depo-Provera by nursing mothers is not known to be associated with any particular hazards. Research on its effects on female babies whose mothers had received Depo-Provera while nursing, is also underway.

Upjohn, the makers of Depo-Provera recommend its use in puerperal women during the first week after delivery, but it can be given at any time in the first six weeks post partum.

Pharmaceutical J., **224**, 110 (26 Jan. 80)

Drug establishments under US FDA

The total number of drug establishments that come under US Food and Drug Administration's regulatory check is 11,400, according to a publication of the agency. Of these, there are 3600 drug manufacturing establishments, 1500 repackaging and relabelling establishments and 200 quality control testing laboratories. The rest 6100 are non-producing establishments, mostly drug warehouses and methadone treatment plants.

PMA Newsletter, **22**, 8 (25 Feb. 80)

REGULATORY NEWS

Bulk drugs production to be monitored

The small scale units now onwards will be required to submit the quarterly production data to Union Ministry of Petroleum, Chemicals and Fertilisers. This is under a directive from the Drugs Controller of India. Production of several vital drugs like antihypertensives and T. B. drugs has come down owing to shortage of basic raw materials.

This has prompted the Central Government to formulate a plan to monitor the production of 16 essential bulk drugs in every quarter in both organised and small scale sectors to avoid their shortages. The drugs include: chloramphenicol, sulphas, analgin, paracetamol, phenyl butazone, PAS, chloroquin phosphate and metronidazole.

The production is reported to have come down also because of lower mark up, i.e. only 40 per cent on bulk drugs. The production which was Rs. 164 crores in 1977-78 is now only Rs. 200 crore for 1978-79. This is not conforming to the projected growth rate. Production of formulations in 1978-79 has touched Rs. 1050 crore against Rs. 900 crores achieved in previous year. It is reported that even this rate would be insufficient to meet the demands of the future that is, Rs. 625 crores for bulk drugs and Rs. 1875 crores for formulations by 1982-83.

Draft bill on narcotics under study

The Union Government in consultation with State Governments is considering a draft bill containing comprehensive legislative proposals on narcotics, drugs and psychotropic substances. The proposals for the bill have been mooted by the Narcotics Commissioner of India. The National Prohibition Council has recommended introduction of total prohibition on all intoxicating drugs and in pursuance of this recommendation, some states are reviewing the problem of drug abuse while a few have already taken some action.

Opium, poppy and cannabis are the most widely used narcotics and Madhya Pradesh, Rajasthan and Uttar Pradesh have permitted by law the cultivation of opium poppy but only in selected areas. Cultivation of cannabis for the production of ganja is permitted in Bihar, Madhya Pradesh, Orissa and W. Bengal, whereas, production and use of its resin (charas) is banned by law. The abuse of both ganja and charas has been reported among mendicants, economically weaker sections, students and even among some affluent sections of society. Though the non-medical use of ganja is allowed in Bihar, Orissa, Madhya Pradesh and W. Bengal in a restrictive manner, the limit of legal possession by an individual is 23 gm. The use of extracts and tinctures of cannabis for non-medical use is not allowed.

India becomes a signatory to WHO charter on medicare

Union Minister of Health and Education, Mr. B. Shankaranand, and WHO Director-General, Dr. H. Mahler, recently signed the Charter of Health Development in South-East Asia.

The Charter has been initiated by WHO to get health care recognised as a part of general development in all the countries. Its objectives, which the signatory countries are expected to follow, include:

Extension of health services to meet the basic health needs of the entire population with priority to the poor sections and areas, self-reliance and better quality of services, utilization of community resources and participation ensuring minimum medical care for everybody.

Prevention and control of diseases according to established priorities.

Provision of safe drinking water to rural and urban population, improvement of facilities for waste water disposal and basic sanitation.

Prevention and control of air and water pollution and promotion of national food and nutrition policies and programmes, taking into account the need for regional and global co-operation.

Reduction of mortality and morbidity among infants and children, improvement of the health of women specially mothers, regulation of fertility to achieve better health and implementation of national population policies.

Alien brand name use to be restricted

The Union Government is contemplating to change the conditions of letters of intent and industrial licences in such a way so that foreign brand names and trade marks can not be used except with the special permission of the government. This will mainly affect consumer goods, drugs and medicines.

Although the Government can right away impose restrictions on the use of foreign brand names and trade marks under the existing laws, a fear of a possible reprisal action by other countries has led it to go in for safer courses.

New health policy for improving rural health

Mr. N. R. Laskar, Union Minister of State for Health has said that Government would concentrate on improving the health conditions of the villages through a viable health delivery system. The matter is under active consideration and a health policy having a distinct rural bias will be finalised shortly. As the doctor-patient ratio in villages is on a very higher side, the services of village social workers could also be fully utilized as they know the local conditions well.

Gujarat methyl alcohol rules implementation put off

The State Government of Gujarat has postponed the implementation of its proposed Gujarat Methyl Alcohol rules (1979) till March 31 (*See* this bulletin, Vol. 2, No. 12, p 307). This comes in wake of strong protests made by user industries of the State (*See* this bulletin, Vol. 3, No. 1, p 3). The State Government had sought to regulate the purchase, possession, use, sale, transport, export and import of methyl alcohol and preparations made with products containing methyl alcohol, though its supply was not regulated so far.

Multinational stops infant formula promotion drive

American Home Products Corporation, a US multinational has assured US House of Representatives that it has stopped the promotion of their products particularly infant formula to mothers in developing countries. The Corporation markets and distributes the infant formula in developing countries. The Corporation has agreed that its promotional drive directly to the public is detrimental to breast feeding.

Relief fund for Japanese sufferers of adverse drug reactions

The Japanese Parliament has passed a bill under which adverse drug reaction sufferers and surviving families will receive relief benefits. The fund will become operative from April, 1980. The fund will function on charges collected from pharmaceutical manufacturers and importers who will be required to pay the fund annually, an amount based on their yearly sales. Many drugs which are outside the purview of this bill include most of the carcinostatic drugs, immunosuppressants, blood preparations such as preserved blood and concentrated human red blood corpuscles, drugs to be exclusively used for manufacture and export, insecticides, rodenticides, disinfectants for medical devices, diagnostic agents not to be directly applied to the human body and gauze, absorbant cotton, bandage and products to be exclusively used as excipients, solvents, bases, flavouring and odour improving agents. These drugs which are not governed by the Relief Fund law shall not be taken into account for collection of charges.

Japan Medical Gazette, **16,** 1 (20 Oct. 79)

Indonesian withdrawal of teratogenic Chinese drug

Malformed babies were born to mothers who took a Chinese herbal medicine, Super Heporine, during early pregnancy. This report from a maternity clinic in Central Java has prompted Indonesian Food and Drug Control authorities to order its withdrawal. The drug is used for the treatment of cycle irregularity, leucorrhoea and anaemia but people were using it as an abortifacient also.

Scrip, No. **459,** 11 (2 Feb. 80)

More countries adopt WHO quality certification plan

The World Health Organisation has signed agreement with thirteen more countries, including India, to participate in the quality certification of pharmaceutical products moving in international commerce. Originally there were 25 countries participating in "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce" and the associated "Good Practices in the Manufacture and Quality Control of Drugs". Drugs controller of India will look after the exchange of information and nine states will care for the "Certificates of Pharmaceutical Products". The states are Andhra Pradesh, Delhi, Gujarat, Kerala, Karnataka, Maharashtra, Tamil Nadu, Uttar Pradesh and West Bengal.

International Drug Regulatory Monitor, No. **80,** 17 (Jan. 80)

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GOVERNMENT OF KARNATAKA DRUGS CONTROL DEPARTMENT

(*Monthly Report: December 1979*)

Details of the Activities

1. *Licences granted*

	Biological drugs	Non-Biological drugs	Homoeopathic	Cosmetics	Poisons
(*a*) For manufacturing	—	2	—	—	—
(*b*) For sale	34	47	2	—	—

2. *Activities*

	Manufacturing	Sales Establishment	Hospital	Drugs (Price Control) Order	Poisons
(*a*) Inspections	14	325	30	52	—
(*b*) Contraventions detected	—	10	—	—	—
(*c*) Samples of drugs drawn (*d*) Samples of Cosmetics drawn	—	10	—	—	—
(*e*) Value of drugs destroyed/confiscated	Rs. 1000/-				

3. *Administration*

	Manufacturing			Drugs sales establishment	Poisons
	Drugs	Cosmetics	Homoeopathic		
(*a*) Licences suspended	—	—	—	20	—
(*b*) Licences cancelled	—	—	—	15	—
(*c*) Licences invalidated	—	—	—	6	—
(*d*) Licencees warned	—	—	—	20	—
(*e*) Applications rejected	—	—	—	5	—
(*f*) Prosecutions launched	(*a*) Drugs and Cosmetics Act 2			(*b*) Drugs (Prices Control) Order 1	

4. *Drugs and Magic Remedies (Objectionable Advertisements) Act*

(*a*) Advertisements scrutinised — 275

(*b*) Prosecutions launched — Nil

(*c*) Contraventions detected — 2

(*d*) Warnings issued — Nil

5. *General Remarks*

Two cases under the Drugs and Cosmetics Act 1940 and one case under the Drugs (Prices Control) Order, 1970 were initiated. Two unlicenced dealers were detected and date expired drugs were seized from a concern.

INDUSTRIAL LICENCES ISSUED DURING NOVEMBER 1979

Sl. No.	Name & address of the Industrial Undertaking	Article of Manufacture	Annual Capacity	Type and No. of Licence
1.	M/s. Boehringer Knoll Ltd., United India Bldg, P. Mehta Road, P. Box No. 1174, Bombay-400 001.	Metronidazole	10 tonnes	New Unit LI: 370/79 dated 13.11.79
2.	C. I. Gandhi, 4, Justice Dwarkanatha Road, Calcutta-700 020.	1. Ampicillin Trihydrate 2. Amoxycillin Trihydrate 3. Cloxacillin Sodium 4. Diclozacillin Sodium	12 tonnes 10 tonnes 7 tonnes 3 tonnes	New Unit LI: 382/79 dated 19.11.79
3.	German Remedies Ltd., Shivsagar Estate, Dr. Annie Besant Road, Worli, Bombay-400 018.	Sulphamoxole	21.6 tonnes (existing) 120 tonnes (after expansion)	Substantial Expansion CIL: 260/79 dated 20.11.79
4.	Raptakos, Brett & Company Ltd., 47, Dr. Annie Besant Road, Worli, Bombay-400 018.	Choline Salicylate	1.50 tonnes	New Article LI: 397/79 dated 26.11.79
5.	Sarabhai Chemicals (Division of Ambalal Sarabhai Enterprises Private Limited), Wadi Wadi, Baroda-390 007.	Propranolol hydrochloride and its formulations	750 kgs.	New Article CIL: 247/79 dated 2.11.79

Contd.

Sl. No.	Name & address of the Industrial Undertaking	Article of Manufacture	Annual Capacity	Type and No. of Licence
6.	S. D. Fine-Chem Pvt. Ltd., 7, Indu Chambers, P. O. Box No. 3232, 349/53 Samuel Street, Bombay-400 003.	1. Bulk Drugs	69 tonnes	New Unit CIL: 225/79 dated 14.11.79
		2. Culture media (dehydrated culture media)	10 tonnes	
		3. Laboratory preparation	25 tonnes	
		4. Laboratory ready media	2 tonnes	
		5. Sensitivity discs	1 tonne	
		6. Biochemical reagent	1 tonne	
		7. Sterile reagent	1 tonne	
		8. Diagnostic agents	4525 kgs	
7.	Synbiotics Ltd., Post Box 129, Wadi Wadi, Baroda-390 007.	(i) Niflumic acid (bulk drug)	5 tonnes	New Article LI: 405/79 dated 29.11.79
		(ii) Niflumic acid capsules	2.5 tonnes (in terms of bulk drug)	
8.	Unichem Laboratories Ltd., S. V. Road, Jogeshwari (West), Bombay-400 060.	Metronidazole	18 tonnes (additional) 24 tonnes (after expansion)	Substantial Expansion LI: 386/79 dated 23.11.79
9.	Shri Y. R. Majumdar, C/o Bakul Aromatics and Chemicals (P) Ltd., Sterling Centre, 4th floor, 16/2, Dr. A. B. Road, Worli, Bombay-400 018.	(i) Theophylline and aminophylline	114 tonnes	New Unit LI: 389/79 dated 23.11.79
		(ii) Synthetic caffeine	66 tonnes	
		(iii) Acetic acid (by-product)	200 tonnes	

NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
1.	*Analgesic*			
	Buprenorphine	Temgesic	Reckitt & Colman	Hong Kong
	Butorphanol	Stadol	Bristol	Hong Kong
	Diflunisal	Dolobid	Merck Sharp & Dohme	Hong Kong
	Diflunisal	Donobid	Merck Sharp & Dohme	Sweden
	Naproxen sodium	Synflex	Syntex	UK
	Zomepirac	Zomax	Ethnor	S. Africa
2.	*Antiandrogenic/Contraceptive*			
	Cyproterone acetate + ethinyloestradiol	Diane	Schering AG	Hong Kong
3.	*Antianginal*			
	Isosorbide dinitrate	Sorbitrate	Stuart	Hong Kong
4.	*Antiarrhythmic*			
	Medigoxin	Lanirapid	Yamanouchi	Japan
5.	*Antibacterial*			
	Cefadroxil	Bidocef	Ciba	W. Germany
	Cefmetazole	Cefmetazon	Sankyo	Japan
	Cefotaxime	Claforan	Hoechst/Glaxo	W. Germany
	Cefoxitin	Mefoxin	Frosst	Canada
	Cinoxacin	Cinobactin	Dista	S. Africa
	Co-trimazine (Trimethoprim + sulfadiazine)	Coptin	Pfizer	Canada
	Dicloxacillin	Diclocil	Bristol	Hong Kong
	Fosfomycin	Fosfocine	Clin-Midy	France
	Mezlocillin	Baypen	Bayer	UK
	Ticarcillin	Monapen	Fujisawa	Japan

(*Contd.*)

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
6.	*Antihypertensive*			
	Metyrosine	Demser	Merck Sharp & Dohme	USA
	Minoxidil	Loniten	Upjohn	USA
7.	*Anti-inflammatory analgesic*			
	Choline salicylate + magnesium salicylate	Trisilate	Purdue Frederick	Canada
8.	*Anti-inflammatory*			
	Fenbufen	Napanol	Lederle	Japan
	Fentiazac	Donorest	Wyeth	Hong Kong
	Piroxicam	Feldene	Pfizer	UK
9.	*Anti-neoplastic*			
	Cisplatin	Platinol	Bristol	Sweden
	Ftorafur	Ftorafur E	Taiho	Japan
	Nimustin	Nidran	Sankyo	Japan
	Vindesine + Mannitol	Eldisine	Lilly	UK
10.	*Antiparkinsonian*			
	Levodopa + benserazide	Madopar	Roche	Japan
	Levodopa + carbidopa	Neodopaston	Sankyo	Japan
11.	*Antispasticity*			
	Baclofen	Lioresal	Ciba-Geigy	Japan
12.	*Antiulcer agent*			
	Pirenzepine	Gastrozepin	Boehringer Ingelheim	Columbia/ Phillipines/ Portugal
13.	*β-Blocker*			
	Sotalol	Sotacor	Bristol	Canada
	Nadolol	Corgard	Squibb	USA
	Acebutolol	Sectral	Rhodia	Spain
14.	*β-Blocker/Diuretic*			
	Atenolol + chlorthalidone	Tenorectic	ICI	Ireland
	Propranolol + hydrochlorothiazide	Inderide	Ayerst	Canada
15.	*Bronchodilator*			
	Hexoprenaline	Ipradol	Chemie Linz	Hong Kong

Contd.

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
16.	*Calcium regulator*			
	Calcitriol	Radanil	Roche	Argentina
	1-α-Hydroxyvitamin D_3 (alfacalcidol)	One-Alpha	Leo	Canada
17.	*Corticosteroid*			
	Methylprednisolone	Solu-Medrol	Upjohn	Japan
18.	*Glaucoma treatment*			
	Dipivefrin	Dipivefrin	Allergan	W. Germany
	Timolol	Timoptic	Merck Sharp & Dohme	W. Germany
19.	*Oestrogen*			
	Quinestrol	Estrovis	Parke-Davis	USA
20.	*Oral Contraceptive*			
	Norethisterone + ethinyloestradiol	Modicon	Ethnor	Australia
21.	*Potassium supplement*			
	Potassium chloride	Kalium Durules	Astra	Canada
	Potassium Chloride	K-lyte/Cl	Mead Johnson	USA
22.	*Thrombolytic*			
	Urokinase	Breokinase	Breon	USA
23.	*Topical antifungal*			
	Exalamide	Hyperan	SS Pharmaceutical	Japan
24.	*Topical corticosteroid*			
	Diflorasone diacetate	Florone	Upjohn	Canada/ S. Africa

CENTRAL FOOD TECHNOLOGICAL RESEARCH INSTITUTE, MYSORE

A PROFILE

Central Food Technological Research Institute (CFTRI), Mysore was established in 1950 with the main objective of development of technology for application to conservation and optimal utilisation of the Nation's food resources. Its activities include technical guidance to entrepreneurs in starting and developing agro-based food and allied industries, solving operational problems of production and quality control and also for training technical personnel.

The Institute has a main multi-disciplinary complex at Mysore and six field stations located at Bombay, Lucknow, Ludhiana, Hyderabad, Mangalore and Nagpur to survey regional problems, to feed-back information needed to identify problem areas and also to serve as extension centres. CFTRI is also housing a sectoral centre of National Information System for Science and Technology, specializing in food science and technology and is known as National Information Centre for Food Science and Technology (NICFOS).

Research and developmental activities are concerned with the following major areas: Analytical Quality Control; Biochemistry and applied nutrition; Fermentation Technology Fruit and Vegetable preservation and processing; Flour milling and baking technology; Industrial development, consultancy, management and information services; Infestation control, pesticides and storage of food grains; Lipids; Meat, fish and poultry products; Microbiology and sanitation; Packaging; Plantation products and flavour; Processing of rice, millets and pulses; Protein technology; Sensory evaluation and Training Programme.

Some note-worthy achievements of the CFTRI are as follows:

Food-grain Protection:

Improved technologies for the protection of food grains have been developed, namely Durofume process for bulk storage, pest-proofing of jute bags, storage in humid areas, small-scale storage, non-poisonous grain protectants, and rodent control. These technologies have been adopted by both private and public sector organisations.

Milling and Processing Techniques for Food Grains:

Mini-rice mill, maize mill and a modern dal mill have been designed to raise milling efficiency and to recover cleaner by-products. Processes for production of edible oil from rice bran and improved method for parboiling paddy, curing of new rice have also been developed.

Fruit and Vegetable Preservation:

Improved post-harvest operations have been evolved to prevent loss of fruits and vegetables while on way to markets from production centres located in remote villages. Processes developed are skin coating of fruits with wax emulsion, antifungal paste to prevent fungal decay in bananas and standardised conditions for dehydration of fruits and vegetables. Techniques such as for the preservation of fruits in the form of juices, syrups, juice powders, fruit bars and fruited cereal flakes; manufacture of papain from papaya and pectin; peel oil and calcium citrate from lime, have also been commercialised.

Plantation Products:

Processes for the production of high quality oleo-resins and oil, dehydrated green pepper (with its characteristic flavour and colour) and monsooned coffee beans have been developed as these products are valuable foreign exchange earners.

Novel Protein Foods:

The unutilised reserves of protein in oil seed are exploited to develop nutritional foods like multi-purpose food, energy food, *bal-ahar* and miltone. Groundnut protein isolate from groundnut has a wide use in protein foods and pharmaceutical products. Many more protein rich products based on different oil seed meals are in the experimental stage.

A process for the production of infant food from buffalo milk has been sold to many industries and now besides ‘‘AMUL’’ a few more brands of dehydrated infant milk are being manufactured in India based on CFTRI know-how.

Convenience Foods:

The Institute has developed a complete know-how for many popular dishes like *idli*, *sambar*, *vadai*, *dosai*, *jilebi*, *rasam*, *bisi bele bhath* and *pulisgare*. These processes are already being commercially utilised.

Fish, Meat and Poultry:

To meet both internal and external demands improved techniques were developed for preserving and processing of fish, meat and poultry. They include production of egg powder, freeze drying and packaging of shrimps and canning of oil sardines.

Out of the total 188 processes/techniques developed, 122 have been transferred to the industry and other users and most of these have been successfully adopted for commercial use.

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BOOK REVIEWS

Biological Substances: International Standards, Reference Preparations, and Reference Reagents

World Health Organization, Geneva, 1979.
Price: Sw. pr. 14.

This volume contains completely revised and up-to-date lists of International Biological Standards, International Biological Reference Preparations, and International Biological Reference Reagents. The biological substances are given in alphabetical order within each group (antibiotics, antibodies, antigens, blood products and related substances, and endocrinological and related substances).

The primary purpose for the establishment of International Biological Standards and Reference Preparations is to provide a means of ensuring uniformity throughout the world in the designation of the potency or activity of preparations used in the prophylaxis, therapy or diagnosis of human disease and that cannot be expressed directly in terms of chemical and physical quantities. Wherever possible, biological substances are assigned International Units (I U).

A secondary purpose of the standards is the facilitation of work out of which clinical application may arise. The World Health Assembly has recommended that Member States of WHO give official recognition to International Standards and Units. International Units are also defined for most of the International Reference Preparations.

The International Biological Reference Reagents provide biological diagnostic reagents of high specificity for the identification of microorganisms or their products (specific antisera), as well as other important biological materials used in the diagnosis of disease. International units are not assigned to these reference reagents, which are not used for the quantitative assay of the activity of biological products.

□

Studies in Drug Utilization: Methods and Applications

Edited by U. Bergman, A. Grimsson, A. H. W. Wahba and P. Westerholm.
World Health Organization, Regional Office for Europe, Copenhagen (WHO Regional Publications, European Series No. 8),
Price: Sw. fr. 20.

In 1969, the WHO Regional Office for Europe arranged a symposium to discuss the problems of rising costs of hospitalization and medical treatment, financing of the health services and of once freely prescribed and used drugs that have, of late, been found to produce harmful, or even lethal, side effects. For these reasons, the whole philosophy of drug utilization called for a thorough re-examination. This led to the formation of the Drug Utilization Research Group, with the aim of coordinating studies in different countries and facilitating international comparisons. In this book, 10 of the participating countries report their experiences so far. They show that with relatively modest means, it is possible to collect and analyse a great deal of data about doctors' prescribing habits, the side effects of the drugs they prescribe and the extent to which patients follow doctor's instructions for taking the drugs. Even in neighbouring countries with similar socio-economic backgrounds, surprising differences in prescribing patterns have been found. The authors examine some of the factors responsible for these differences and give examples of various applications to which the data may be put.

Two chapters deal specifically with international comparisons of drug utilization, taking as examples antidiabetic drugs and psychotropic drugs. The aim of the book is, in fact, to stimulate such international comparisons and a concluding chapter looks at ways in which the value of drug utilization studies might be enhanced in the future.

▭

World Directory of Medical Schools. Fifth Edition.

World Health Organization, Geneva.
Price: Sw. fr. 30.

The Directory contains information on undergraduate medical education, and lists the institutions that provide it, in more than 100 countries. The data presented is for the academic year 1975/1976 but an effort has been made to keep the volume as up to date as possible. The information is based primarily on answers to a WHO questionnaire circulated to schools through their respective governments; before publication, the individual entries were transmitted to the governments in question for verification and approval.

For each country there is a general statement on the pattern and administrative structure of undergraduate medical education. Criteria and process of student selection, the different types of curriculum design, instructional methods used and the procedures for evaluating student performance, have been made available. An effort has also been made to present the salient features of the requirements governing qualification, registration, and the granting of the licence to practice.

Each country statement is followed by a tabulation of the undergraduate medical schools in the country concerned. The names and addresses are, for the most part, given in the national language. Other columns in the table list the year instructions started, the number of teaching staff, total enrolment, the number of admissions, and the number of graduates. A series of annexes present the following information: data on registration and licensure for medical practice in a number of countries without medical schools; an example of a medical school's general objectives; definition of "integration" in the medical curriculum; and a comprehensive list of the members of medical schools in 1955, 1960, 1970 and 1975, by country and area.

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DRUG INDUSTRY

General News

Vital drugs to be imported, if necessary

According to Mr. Veerendra Patil, Minister for Petroleum, Chemicals and Fertilizers, the Government will immediately go in for import of vital drugs, whenr ever a shortage occurs. Already certain vital drugs are being imported in large quantities to meet shortages. The Government is committed to the supply of essential drugs to the public in areas of shortages.

The minister told the parliament that there had been a shortfall in the production of certain vital life saving drugs including PAS and its salts (an anti-TB drug) during the period April to December last as compared to their production in the corresponding period of 1978. He admitted that though shortage of some brand products has been reported equivalent brands are available. The shortfall in production is due to a number of reasons such as power cuts, industrial unrest, non-availability of packaging materials like aluminium foils, non-availability of some basic raw materials like caustic soda, ethylene oxide and also the escalation in the cost of other inputs.

Foreign drug firms to dilute equity

Seven foreign drug companies which are currently having 100 per cent foreign equity and have no high technology bulk drug manufacturing activity, will have to reduce their foreign equity to 40 per cent. These companies are Beecham India (P) Ltd., Copper Lab, GW Carnrick, Grove Products Ltd., John Wyeth Bros, May & Baker India Ltd. and Smith Kline and French.

Apart from these seven, four more have been asked to bring down their equity to 40 per cent. These are Abbot Laboratories having 100 per cent foreign equity, Anglo French Drug Co. having 80 per cent, C. F. Fulford having 100 per cent and Indian Schering having 88.6 per cent. Two companies which have already diluted their foreign equity to 40 per cent are Carter Wallace and Nicholas of India Ltd. Thus out of 34 companies, whose claims of high technology were considered by an expert panel, cases of 21 are still to be resolved.

The high technology claims of Richardson Hindustan with 55 per cent foreign equity and Whiffen (India) Ltd. with 50 per cent foreign equity have been rejected and they have been asked to bring down their foreign equity to 40 per cent. This leaves only with 19 companies, including Glaxo, Sandoz and Parke Davies, for which the decision has to be taken. But three of these companies claiming high technology use namely, Organon, Unisankyo and Geoffrey Manners have less than 50 but more than 40 per cent foreign holding. They will also be asked to go down to 40 per cent, if their claim is not accepted.

Meanwhile, Goverment has already taken action to work out the norms for the dilution of foreign equity. It is pointed out that several bulk drugs involve only one to three steps simple reactions. This may help government to ask the companies to reduce their foreign holding in terms of FERA guidelines. Besides, when schemes of expansion of several companies, now pending with the government are cleared they would be required to further dilute their foreign equity. It is thus hoped that government would soon be able to achieve its major objective of Indianising the foreign drug multinationals.

Price rise of drugs not allowed after March '78

Mr. Veerendra Patil, the Union Minister for Petroleum, Chemicals and Fertilizers told parliament that the Government has not allowed any increase in the prices of price-controlled formulations including encapsuled drugs after March 1978. On the contrary, following the notification of "leader prices" the manufacturers of category I and II formulations whose prices were above the leader prices were required to bring down their prices below the leader prices level. However, certain formulations were exempted from the price fixation including category III and IV formulations manufactured by drug units having a sales turnover not exceeding Rs. 50 lakhs.

The minister said that government would fix drug prices in such a way that drugs of mass consumption and those of an essential nature are available at comparatively cheaper rates and at the same time the manufacturer also gets, on an overall basis, a fair return for his products. The Bureau of Industrial Costs and Prices (BICP) is studying the price structure of several bulk drugs including the life saving ones. Based on these studies the price structure would be revised, if necessary.

Drug units increase basic prices

Some drugs units, mostly foreign controlled, have jacked up the prices of category IV drugs, pending implementation of new Drug Price Control Order. There are over 30 drug formulations in this category, which includes: anabolics, antidepressants, antidotes, male hormones, nasal decongestants, surgical dressings, sweetners and throat lozenges. Drug formulations in this category are not subject to any price control as these are considered non-essential.

The revision of prices amounts to a violation of Drug Price Control Order 1970, under which no drug item is exempt from price control and which still holds good pending a final decision on the new DPCO 1979. The 1970 order has only two drug classifications, namely, essential drugs and non-essential drugs. Essential drugs are allowed a maximum mark up of 75 per cent, whereas, non-essential drugs have a maximum mark up of 150 per cent.

Drug Price Control Order 1979 allows a maximum mark up of 40 per cent on drug formulations in category I, 55 per cent in category II formulations and 100 per cent for category III. Category IV drugs are exempted from this order so that units could offset the losses arising out of a reduction in mark ups in essential drug formulations falling in categories I and II. But the industry considers this to be very nominal as category IV products are quite few.

The report quoting some industry sources further says that industry has been compelled to raise the prices because of continuing delay by government in allowing price hike, despite of a sharp rise in the prices of various raw materials.

More funds for Indian systems of medicine

A provision of Rs. 642 lakhs has been made in 1980-81 budget for the development of Indian systems of medicine and homoeopathy. It is Rs. 205 lakhs more over last year's allotment of Rs. 437 lakhs and of this amount Rs. 306 lakhs will go for Ayurveda and Siddha, Rs. 32 lakhs for homoeopathy and Rs. 21 lakhs for unani, nature cure and yoga.

Measures suggested for increased export of herbs

A study on the export prospects of medicinal herbs to USA, West Germany and Japan carried out by the Indian Institute of Foreign Trade, has suggested a few steps like (a) fixation of minimum export price and (b) improvement in the quality of medicinal herbs, to boost the export of such herbs (*See* this bulletin Vol 3, No. 3, p 58).

According to the study the export of medicinal herbs increased six-fold from Rs. 43.9 million in 1972-73 to Rs. 246.1 million during 1977-78. The export was mainly of cultivated psyllium husk and seeds, which when dried are used as emollient, demulcent and laxative in the treatment of chronic constipation, amoebic and bacillary dysentry. Senna leaves and pods are also attracting export market. There is also a vast scope for the increased exports of other herbs like vallarian roots, squills, ruhbab, berberine, ipecac roots and powder, dried roses, aloe, cassia, *rauwolfia serpentina*, liquorice and coptis roots, ephedra herb extract and gallstone.

The study has suggested that the industry should be helped in the extraction of active principle from the herbs. Half of the total senna leaves and pods exported is used for extracting calcium sennoside by the importing countries. So, methods to extract calcium sennoside of 60 per cent purity and also efforts to increase the sennoside contents of the pods and leaves should to taken up. Moreover the minimum export price of senna should be announced every year before the start of the season in consultation with representatives of growers, processors, exporters and export promotion councils. Presently, 80 per cent of senna is marketed as "Senna tea" after sizing and fumigation. If instead of this, senna leaves and pods are sized according to specifications, the per unit value realisation will go up.

The report also called for a collaborative arrangement between IDPL and Japanese pharmaceutical industry for the marketing of bulk laxative formulations in that country.

Drug units resent benzene, toluene price hike

Indian Chemical Manufacturer's Association has represented to Union Ministry for Petroleum, Chemicals and Fertilizers against an abrupt and excessive hike in the price of benzene and toluene by Indian Oil Corporation. Benzene price has been increased by 19 per cent, that too with retrospective effect. Similarly, toluene price has also been raised.

Benzene is a basic raw material for manufacturing a large number of items from vital drugs and intermediates, pesticides, dyestuffs, plastics to various important organic chemicals. Toluene is also used as a raw material for many items. The association while appreciating the need for price increase, considering the current international prices of crude oil, has said that no increase in the prices of these two chemicals for the last six years had given stability to the units. But this quantum of hike and that too with retrospective effect has given them a rude shock.

The memorandum points out that the benzene users will not be in a position to recover the additional costs for the materials already sold out and also they will find it difficult to bear this extra burden.

Sugar at controlled rates for drug firms

Under the instructions of Ministry of Petroleum, Chemicals and Fertilizers the Food and Drug Administration of Maharashtra has asked the drug firms to furnish their requirement of sugar for the year 1980-81. The instructions follow the representation made by Indian Drug Manufacturers Association to the Ministry over the shortage and prohibitive prices of sugar.

According to the representation, the drugs units were paying Rs. 5 per kg of pharma-grade sugar when the retail price of sugar in open market was Rs. 3 per kg. But now since the retail price is ruling above Rs. 5, the units have to pay around Rs. 9 for pharma grade sugar. This has affected the prices of formulations which are based on the levy price of sugar. The monthly requirement of the sugar by units will be around 2100 MT. IDMA had pleaded with the Government to reintroduce the earlier system when it used to get sugar at controlled prices.

Drug Industry in South East Asian Countries

A delegation sponsored by CHEMEXCIL visited South East Asian countries in December 1979. The drug industry in this delegation was represented by Dr. G. K. Nair and he has gathered the following impressions about the drug industry of these countries.

Burma has only one wholly state owned pharmaceutical unit *viz.*, the Burmese Pharmaceutical Industry. The production of this unit is so less that the country has to import about $ 20 million worth of drugs and pharmaceuticals every year. All drugs are canalised through Mynama Export/Import Corporation and the major exporters are USA, W. Germany and Japan, the indigenous production being limited to about 180 formulations only. Although Burmese importers know of Indian products but they are not happy with Indian exporters as they do not adhere to the delivery schedule.

South Korea has a well developed pharmaceutical and formulation industry. Of late, the import of formulations is increasing in this country and there is a possibility of export of Indian raw materials to this market.

Taiwan has a fairly well developed pharmaceutical industry which is mainly limited to formulations. The country has to depend upon USA, W. Germany, Holland, Belgium, Denmark and Japan for a wide range of drugs. The Taiwan Supply Burfar handles the import of drugs and pharmaceuticals for state organisations and public enterprises. There are three categories of imports: (*i*) prohibited, (*ii*) controlled, and (*iii*) permissible. Most of the items except narcotics are covered under the last category.

Philippines has many multinationals operating there. A major local company, the United Laboratories Inc. is the largest manufacturer of drugs and pharmaceuticals. The country's requirements of raw materials are met through imports. For marketing finished formulations the products have to be registered with the Food and Drug Administration and FDA holds complete control over drugs and pharmaceuticals, quality.

Cabinet committee to study bulk drug prices

The Union Government has set up a cabinet sub-committee to consider the question of revision of prices of bulk drugs in view of the rise in cost of inputs.

It is, however, speculated that Government is not favourably inclined towards the proposal for an increase in prices since it would automatically raise the prices of various formulations and drugs and cause hardship to the common people.

Drug famine feared

The *Eastern Pharmacist* in its March, 80 issue has forewarned the Central Government of a drastic fall in the production of all types of vitamins, analgesics, antipyretics, antitubercular, antimalarial, antidysentery, antidiabetic, antiasthamatic, anaesthetics and many other essential drugs, if certain corrective measures like amendment of Drug Prices Control Order 1979 and other price reforms are not undertaken. The production in most of the cases has already gone down by 20-70% of the target. Even the public sector undertaking the Indian Drugs and Pharmaceuticals Ltd. has reported a fall in its production capacity. Already several antihypertensive and antianginal drugs are not available in market. Although the Government is saying that substitute products are available which have similar pharmacological actions, many patients respond only to a certain drug and not to all drugs even if they have similar pharmacological action.

Many factors are responsible for this unfortunate development. First, the Drug Price Control Order 1979 which curtails the profit margins on essential drugs to a level which forces most of the manufacturers to curtail production. Second, erratic supply of raw materials by the canalising agency. Supplies which should be released on quarterly basis are released on a cumulative basis covering more than one quarter, making it difficult for the units to obtain bank credits as it becomes a transaction involving huge money. Third, instead of allowing the units to utilize their excess production capacity by manufacturing certain drugs, Government is going for their import. Fourth, the implementation of new drugs policy is so slow that many leading units are in a quandary in respect of capacities of production of individual items.

The article suggests scrapping of the new price control order. Though this order has the potential of containing drug price rise it hardly gives any scope for growth. Moreover the Bureau of Industrial Costs and Prices has no requisite infrastructure and competence to carry out all the responsibilities it has been entrusted to under the new order. The industry wants that recommendations of the Hathi Committee should be implemented as it provides sufficient incentives to industry to develop in a steady and sustained manner besides offering elastic scheme of price control. The Government's ignorance to this committee's recommendations has saddened the industry. Further the recommendations of Chavda Committee, as to what categories of drugs should be canalised and how the prices should be determined, should also be implemented. All these measures will surely contribute towards the healthy growth of the drug industry and will save the country from facing a serious crisis of drugs shortages.

Ayurvedic products for Japan

A Japanese trade team has shown interest in importing ayurvedic toothpaste and turmeric vanishing cream from India. According to a team member, Japanese consumer is being attracted towards Ayurvedic products but an order can only be placed when Japanese Food and Drug Administration clears the products. But the clearance is not difficult to get as US Food and Drug Administration has already cleared the products and that Japanese usually emulate US FDA.

Japan to manufacture more pharmaceutical products

The Japanese Ministry of Health and Welfare has given approval for the manufacture or import of following sixteen major pharmaceutical products:

Alprostagyl α-cyclodextrin inclusion compound, Baclofen, Benserazide hydrochloride, Bentiromide, Betamethasone dipropionate, Cefatrizine, Cefmetazole sodium, Cefoxitin sodium Glycyrrhizin/Glycine/Cysteine, Lithium carbonate, Methylprednisolone sodium succinate, Miconazole nitrate, Picosulphate sodium, Protizinic acid, Ticarcillin sodium and Tiopronin.

Japan Medical Gazette, **17,** 4 (20 Jan. 80)

Japanese drug production exceeds Y 3 Trillion

The Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, Japan has announced that drug production during 12 months period of 1979 was Y 3,033,349 million. This is 8.6% more than the previous year's value of Y 2,793,878 million. Still the 1979 rate of increase is not noteworthy as it has dropped below the 10% level for the first time in the last four years. The rate was 13.7% to 20.6% higher in the years 1976 to 1979.

The value for the total production of quasi drugs in 1979 was Y 273,305 million, surgical dressing Y 48,019 million and medical devices Y 539,549 million.

Japan Medical Gazette, **17,** 1 (20 March 80)

Japanese firms spent $ 640 million on R&D in 1978

The top 72 drug companies of Japan spent $ 640 million (7.74% of total drug sales) on R&D in 1978, according to a survey conducted by the Japan Pharmaceutical Manufacturers' Association. Of this figure, expenditure on basic research accounted for 17.9% and applied research for 23.4%. Investment in R&D equipment was $ 63.4 million.

In 1978 personnel costs accounted for 51.6% of the total R&D expenditure. The number of researchers employed by 72 companies increased from 14,770 in 1976 to 15,624 in 1978.

Scrip, No. **469,** 11 (8 March 80)

Algeria to go in for small pharmaceutical plants

According to Mr. M. Rafik Morsly, Managing Director of Pharmacie Centrale Algerienne (PCA), the Algerian government is planning to set up several small scale pharmaceutical plants during the next five year plan (1980-84). Initially the government had planned to build one large plant employing 2500 persons but now several smaller plants, each employing 350-400 workers and costing about $ 44.4 million would be set up.

At present locally produced pharmaceuticals account for 17% of national consumption PCA is responsible for distribution and production of pharmaceutical products and its three plants have a total turnover of $ 31.6 million. The country is highly dependent on multinationals. The local production of pharmaceutical goods would be in line with government policy to reduce dependency on foreign assistance and also it will effect a saving in foreign exchange spending.

Scrip, No. **465,** 11 (23 Feb. 80)

France world's fourth largest producer of drugs

French shipments of pharmaceutical preparations for 1979 amounted to $ 4854 million thus making it the world's fourth largest producer of medicines. The average annual growth rate of shipments between 1973 and 1979 has been reported to be 12.3. The 1978 figures indicate that top 100 out of 390 companies accounted for 85% of the industry's sales and 47% of all sales coming from foreign owned manufacturers.

In 1978-79 the added value of the pharmaceutical industry was 30% of sales and 80% of this amount represented personnel costs. In 1978, the drug companies R & D expenditure was $ 394 million' (8.9% of sales). The pharmaceutical exports amounted to $ 895 million in 1979. The largest French pharmaceutical group was Rhone-Poulenc followed by Roussel Uclaf and Sanofi, each reporting sales more than Fr 1,000 million. The Rhone-Poulenc ranks 12th in world's top companies The companies reporting sales between Fr 500 and 1000 million were Sandoz, MSD-Chibret, Clin-Midy and Servier.

Scrip, No. **473**, 5 (22 March 80)

BPI survey reveals German companies inputs and outputs

According to a BPI survey, the top 25 wholly or partly German owned pharmaceutical companies spent world-wide, in 1979, DM 1,460 million on research and development. In 1978 the domestic spending in pharmaceutical R&D was DM 1500 million but it includes German spending by foreign owned companies. This does not include investment in buildings or equipment, quality assurance, scientific information or sampling. The companies spending DM one million or more on R&D account for 45% of the West German pharmacy market. In addition to this ten companies specializing in specific therapeutic areas account for the 50% of the domestic market and 90% of the export market.

According to the survey, 358 new substances are in clinical trials, 14% from companies having a turnover of less than DM 45 million/year and 60% from having sales of DM 150 million/year and above. Of the 11,822 drug patents applied for in Germany between 1964 and 1978, 3% were from companies with sales below DM 45 million and 89% from those having sales above DM 150 million. Lowest sales group contributed 13% of the total scientific publications where as highest sales group published 54%·

Scrip, No. **467,** 3 (1 March 80)

Combination drugs dominate W. German prescriptions

According to Dr. Franz-Josef Oldiges, the general secretary of Bundesverband der Ortskrankenkassen, 70% of all products prescribed in W. Germany were combinations while only 30% were single substances. Dr. Oldinges, who was addressing a symposium said that this is exactly the reverse of the situation in the US, the Netherlands, the UK, Sweden and few more countries. The high proportion of combination products could be attributed to manufacturer's promotion which the doctors usually do not check. Another speaker Dr. Harter of the University of Heidelberg contradicted a widely circulated belief that general practioner needs only, on an average, 200 drugs to cure all the ailments. In his views the mankind requires between 500 and 1000 drugs, all used regularly.

Scrip, No. **474,** 4 (26 March 80)

ASEAN countries identify areas of common interest

A pharmaceutical workshop of ASEAN countries, held in Manila, after deliberations over major issues faced by the pharmaceutical industry has identified some areas of common interests. These are: common drug registration procedures; common trade tariffs, price level; a list of essential drugs; the quality, safety and efficacy of drugs; national drug policies; closer rapport with the pharmaceutical professions; an ASEAN centre for pharmaceutical technology, industry support for the continuing education of the relevant pharmaceutical professions; raw material manufacture and participation in government legislation.

It has also been agreed to establish a joint organisation comprising both manufacturing and marketing companies which will be called ASEAN Pharmaceutical Business Group.

Scrip, No. **474,** 9 (26 March 80)

Pharmaceutical opportunities in developing countries

Information Research Ltd., London has undertaken a major study entitled "opportunities for pharmaceuticals in the developing world over the next twenty years". The study considers the relative importance of those factors which will influence the use of pharmaceuticals over the coming years in the various countries of the world and predicts the size of the future demand for each major product group over the next two decades.

The health plans and future requirements of the important developing countries are considered in world wide context. The nature and timing of the evolution of national pharmaceutical industries of these countries as well as, the sources of finance necessary to implement these plans are also covered. Effects of present and forthcoming legislations and regulations on world pharmaceutical market are also discussed. Guidelines for successful marketing in these countries are also outlined.

Further details about the study (Price £ 130) can be had from Information Research Ltd., Bond Street House, 14 Clifford Street, London W1X 1RE.

Scrip, No. **467,** 11 (1 March 80)

Economic Community of West African States (ECOWAS) established

The 15 West African countries have organised themselves into Economic Community of West African States (ECOWAS) similar in concept to European Economic Community (EEC). Nigeria which gave a lead to other countries will house the headquarters of the new organisation at Lagos. The member states are : Dahomey, The Gambia, Ghana, Guinea, Guinea Bissau, Ivory Coast, Liberia, Mali, Mauritania, Niger, Nigeria, Senegal, Sierra Leone, Togo and Upper Volta. Since Nigeria has the largest drugs, medical devices and cosmetics market among these nations, its legislations and regulations may set the standards for pharmaceutical and related products in all the countries of ECOWAS.

International Drug Regulatory Monitor, No. **81,** 1 (Feb. 80)

WHO membership swells to 152

The Seychelles, a group of islands north of Malagasy Republic has become the latest member of WHO by accepting the WHO constitution and thereby, depositing its instrument of acceptance with UN Secretary General.

International Drug Regulatory Monitor, No. **81,** 18 (Feb. 80)

Company News

Bayer's profits decline

Bayer (India) has suffered a setback in its working with its gross profits declining by 11 per cent from Rs. 6.72 crore for 1978 to Rs. 5.98 crores during 1979. The fall in profits is despite the rise of 12 per cent in sales from Rs. 44.39 crore to Rs. 49.79 crore. The net profit for 1979 amounts to Rs. 2 crore against Rs. 2.31 crore for the previous year.

The setback in profitability is attributed to the increase in input costs without any corresponding rise in selling price.

Boots earns more

Boots India increased its sales from Rs. 14.12 crore in 1978 to Rs. 17.04

crore during 1979. Its gross profit is up at Rs. 2.02 crore against Rs. 1.91 crore. The profit after tax amounts to Rs. 76.29 lakh against Rs. 73.03 lakh for the previous year.

Drug project for Pondicherry

Pondicherry Industrial Promotion Development and Investment Corporation is going to set up a drug formulation plant in Pondicherry in collaboration with Hindustan Antibiotics Ltd. The plant will cost Rs. 1.5 crore.

Gujarat Analgesics Ltd. to manufacture aspirin

A new company, Gujarat Analgesics Ltd., has been formed to manufacture 500 tonnes of salicylic acid and 300 tonnes of aspirin per annum. Gujarat Industrial Investment Corporation Ltd., which is promoting this venture has signed an agreement with Gujarat Salicylates Pvt. Ltd. The project will have an annual sales turnover of Rs. 1.7 crore and will be located at Ankleshwar, a backward district of Gujarat.

Salicylic acid is much used in the manufacture of aspirin. Its use has also been found as antiseptics, disinfectants, direct acid dyes, rubber industries and perfumery. Similarly aspirin which is used extensively as antipyretics and analgesic has found use as a life saving drug in disorders caused by blood clots.

German Remedies fares well in 1979

During 1979 the German Remedies has maintained dividend at 14 per cent and sales and profits are also more compared to the previous year. Sales have increased by over 22 per cent from Rs. 14.28 crores in 1978 to Rs. 17.48 crores this year. The pretax profit for the year is Rs. 2.62 crores against Rs. 2.40 crores last year. After depreciation of Rs. 21 lakhs, investment allowance of Rs. 3.13 lakhs and taxation of Rs. 1.86 crore the net profit comes out to be Rs. 76.59 lakhs against Rs. 72.05 lakhs in the previous year.

KAPL to set up antibiotics plant

Karnataka Government has approved of the establishment of Karnataka Antibiotics and Pharmaceuticals Ltd. with an authorised share capital of Rs. 1 crore. The KAPL will set up in a village of Bangalore district a plant to produce antibiotics. The State Government will contribute Rs. 32 lakhs towards it.

Hindustan Antibiotics Ltd. and Industrial Development Bank of India have agreed to invest Rs. 58 lakhs and Rs. 10 lakhs respectively in the share capital of the company.

Miles India Ltd sales increase

Indian affiliate of the US company Miles Labs Inc., the Miles India Ltd. has reported 1979 sales of Rs. 64 lakhs registering an increase of 88.2% over 1978's sales of Rs. 34 lakhs. Gross profit amounted to Rs. 2.86 lakhs, compared to a loss of Rs. 15.4 lakhs in 1978.

Pfizer India profits go down

Despite a moderate increase in net sales to Rs. 46.37 crores from Rs. 43.53 crores in the year ending 1979, the pretax profit of Pfizer India has declined by nearly 10 per cent, to Rs. 6.97 crores from Rs. 7.32 crores last year. After taxation of Rs. 4.26 crores the net profit is slightly up, Rs. 2.71 crores compared to Rs. 2.64 crores of previous year.

Ranbaxy Laboratories profits up

Ranbaxy Laboratories have shown considerable rise in sales and prices for the year 1979. The sales turnover has gone up by 24.5 per cent to Rs. 13.59 crores. The gross profit spurted to Rs. 1.298 crore from Rs. 86 lakhs in the previous year.

After providing Rs. 18.66 lakhs for depreciation, Rs. 5.69 lakhs for investment and Rs. 46 lakhs for taxation, the net profit works out to be Rs. 59.49 lakhs; Rs. 52.23 lakhs have been transferred to general reserves.

Searle (India) to diversify

Searle (India) Ltd. is diversifying into pesticides field. It is going in for the manufacture of pyrethroids for which a letter of intent has already been issued. Manufacture of these pesticides would be taken up at its new plant in Ankleshwar which has a capital outlay of about Rs. 2.5 crore. Several bulk drugs and formulations will also be manufactured at the new plant at an additional investment of Rs. 3.5 crore. Ankleshwar plant is expected to be fully operational by 1982 and that year Searle expects its sales to reach Rs. 12 crore.

The company is also going to introduce a few new drugs. It has been granted a letter of intent for producing Norpace, a life saving drug which is in use in USA for the last two years. It is used specifically as an antiarrhythmic agent for disordered rhythms of heart and there is no substitute drug available having the similar effects. Though the drugs procainamide and quinidine have effects similar to Norpace, they are not prescribed freely due to their highly toxic side effects. Norpace is classified as a class I antiarrhythmic in the pharmacological profile. Results of clinical trials have confirmed its much lower toxicity as compared with quinidine and procainamide. This drug will be manufactured at the Ankleshwar plant. The licenced capacity in the beginning is one tonne/year.

Sunil-Synchem to expand

Sunil Synchem has plans to increase its production to 900 million empty hard gelatine capsules from the present 500 million capsules per year. The company has obtained licence to produce eight capsule making machines per year.

The company has also plans to diversify into the manufacturing of methyl dopa a drug used to cure hypertension. This will result in a saving of Rs. 1.3 crores in foreign exchange from mid 81 onwards, when the production will start. In the drug formulation field, the company proposes to manufacture different Ayurvedic drugs and sell them in tablet forms.

Research and Development

Artificial lungs made from plastic

An artificial lung made up of 30,000 fine hollow polypropylene tubes has been placed in about 40 patients in a hospital in Japan. This new device could replace the conventional artificial lungs which involve the risk of red blood cells being damaged or of clotting.

The new lung is easier to handle and is more efficient, according to its developer. In this blood is separated from the oxygen by a thin film of porous material. Each of the 20 cm long and 250 mm wide tubes has very fine pinholes along its length. The holes are too small to allow blood to leak out but permit carbon dioxide to escape and oxygen to enter. The greater number of hollow fibres means that there is always a large surface area exposed to the oxygen flow.

Insulin from buffalo

A team of veterinary doctors, led by Dr. A. Mantri, at Bombay Veterinary College, has extracted insulin from the pancreas and lungs of healthy buffaloes. The raw materials, pancreas and lungs, were collected within 20 to 30 minutes of the slaughter and preserved in deep freeze. The insulin and heparin were successfully extracted using a process standardised for the laboratory scale preparation. The products, purified to the last stage, in yield and activity were found to be comparable to the standard ones available in the market.

New drugs to cut TB cure period

Many patients who have no patience to continue treatment through the full 18 to 24 months period required for the cure of TB, can now go for a new therapy which cuts the cure period to just half i. e. between 9 and 12 months.

The new cure utilizing two powerful drugs Rifampicin and Isoniazid has been reported by the scientists from Centre for Disease Control, Atlanta. This therapy has already been tested at many centres in USA, Asia and Africa.

Non-toxicity claim of thioproline challenged

A group of Paris based scientists has challenged the claim of Spanish clinicians Drs. A. Brugarolas and M. Gosalvez that thioproline (thiazolidine-4-carboxylic acid) is effective in treating epidermoid carcinoma possibly by inducing reverse transformation of tumour cells to normal cells.

According to the Paris group, thioproline is fairly well known in France as Hepaldine and is used for the treatment of hepatic and biliary disorders. Acute intoxication of this drug has been reported in children Of the 78 cases reported, 23 have resulted in seizures while 4 had a fatal outcome.

Any plan to try thioproline in the treatment of solid tumours should be weighed against the potential toxicity of the drug. In adults the seizure is reported with a dose of 60 mg/kg, whereas in children it is 30 mg/kg and above.

Meanwhile a drug multinational Hoffmann-La Roche has concluded an agreement with Prof. Gosalvez for the further development of thioproline therapy in treatment of cancer patients.

Scrip, No. **466**, 12 (27 Feb. 80)

Cyclacillin—a new oral penicillin

US Food and Drug Administration has approved Cyclacillin (Cyclapen', Wyeth Labs) a new semisynthetic aminopenicillin for the treatment of respiratory tract infections, otitis media, skin and soft tissue infections and urinary tract infections caused by some specific organisms.

The drug is being promoted as having fewer adverse effects than the closely related ampicillin. The antibacterial spectrum is almost identical to ampicillin and amoxycillin, but *in vitro* cyclacillin is 25-60% less active than ampicillin against many organisms. Also β-Lactamase producing staphylococci and *Haemophilus influenzae* resistant to ampicillin would be resistant to cyclacillin. It has no advantage over penicillin G or V for streptococcal sore throats. A double blind trial by the manufacturer has revealed cyclacillin and ampicillin to be equally effective when tested for urinary tract infections caused by *E. coli* and *Proteus mirabilis*, respiratory tract infections and otitis media caused by streptococci, pneumococci and *H. influenzae*, and staphylococcal and streptococcal skin and soft tissue infections. The incidence of side effects reported, respectively, for cyclacillin and ampicillin by the manufacturer are: diarrhoea in children on suspension, 9% and 19%; diarrhoea in adults on tablets, 3.7% and 10.8%; rashes in all patients, 1.7% and 3.1%. Patients allergic to other penicillins are considered allergic to cyclacillin also.

Inpharma, No. **226**, 2 (1 March 80)

Human growth hormones produced by recombinant DNA technique

Two groups of scientists have succeeded independently in producing human growth hormone using recombinant DNA techniques. One group is at the University of California at San Francisco, the other at Genentech, south San Francisco, a commercial concern working on recombinant DNA procedures to make molecules of potential therapeutic value.

Human growth hormone (HGH) is used for the treatment of hypopituitary dwarfism and a number of other growth disorders. It can be obtained at present only by extracting it from human pituitary glands obtained from cadavers. Obviously, it remains in short supply. If more HGH were available, successful therapy for a number of other disorders could be investigated, including stress ulcers, abnormal thinning of the bones in elderly women, failure of bone fractures to heal, the management of acute liver failure and the stimulation of liver cell regeneration.

However, unlimited supplies of HGH produced by DNA recombination technique are not likely to be immediately available. For instance, neither group has assayed its agent for biological activity and also there is a significant difference between the products obtained by the two research groups. The California scientists have obtained only a pro-HGH molecule with some non-HGH peptides attached to it, which will have to be removed before the molecule can be expected to be biologically active.

The Genentech group has produced the HGH molecule only. Thus, say the Genentech scientists, their molecule is potentially more useful than the University of California's product.

The gene used by Genentech to get the HGH molecule was in part synthesized in the laboratory and in part derived from natural sources. The bacterium used to synthesize HGH is *Escherichia coli.* Dr. David Goed of Genentech says that it is possible to make 100,000-200,000 copies of the molecule per cell as it depends on the concentration of the bacteria.

The next step is to test the synthesized HGH for biological activity. Genentech intends to conduct tests in collaboration with the Swedish pharmaceutical firm, A. B. Kabi. Kabi which funded Genentech's programme is one of the world's major extractors of the hormone, and is experienced in HGH. The university group also intends to test its molecule for biological activity, but concedes that its agent first must be purified and the unwanted amino acid residues removed. Genentech's scientists predict that it would take about three years for the synthetic agent to become available for clinical use.

American Pharmacy, NS **19**, 42 (Dec. 79)

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Interferon

A relatively new drug, it is considered highly effective not only in the prevention and cure of chronic hepatitis and other viral diseases but also in cancer treatment. The term 'Interferon' was coined by a team of UK scientists Drs. A. Issacs and J. Lindenmaan, who had worked out its synthesis in the year 1957. It is a macromolecular glycoprotein (Mol. Wt. 13000-125000) formed by the action of a virus and the host cell and produces in the cell a substance which inhibits selectively the multiplication of viruses without directly affecting them.

Interferon is believed to be practically non-toxic and non-antigenic. There is, so far, no report of serious adverse reaction even after prolonged use of its high doses. The conventional method of getting interferon is from white blood cells. For the production of 30 to 60 million units of interferon, blood of about 100 donors is required.

● **Japanese firms to develop interferon:** The Green Cross Corporation and Toray Industries Inc., have been entrusted by the New Technology Development Corporation of Japan for the development of interferon. At present, two types of interferon are known: (*a*) Type L derived from human leucocytes and (*b*) Type F from human diploid cells. Under this contract, the Green Cross will develop the type L and Toray, type F. If the product development is successful then viral diseases which are at present partially controlled by vaccines will be possibly fully controllable and treatment for malignant neoplasm made possible.

● **Interferon for trial in hepatitis:** Interferon obtained from white blood cells of donated blood will be used for clinical evaluation in hepatitis (*Japan Medical Gazette*, **17,** p 1, 20 Jan. 80). For this purpose one thousand million units have been presented by the Central Blood Centre Research Team of the Japanese Red Cross Society to the intractable hepatitis research team of Japanese Health and Welfare Ministry.

● **Searle and Mochida to market interferon in Japan**: GD Searle & Co. and a Japanese drug firm, Mochida have agreed jointly to develop and market interferon in Japan (*Scrip.*, No. **469,** p. 8, 18, March 80). Searle will supply Mochida technical know-how and information on fibroblast and lymphoblastoid interferon and will also help in developing production capability for interferon by tissue-culture methods. Mochida will be granted the sole licence for Searle's Japanese patents, patent applications and know-how for interferon.

Mochida, in return, will undertake jointly with Searle the programme for clinical research and development of interferon. They will file jointly an application for the registration of new products or claims emanating from such investigations. Mochida will also give Searle the right of first refusal on a new pharmaceutical product developed by it and will manufacture interferon on behalf of Searle, if requested. The Japanese company will also pay an undisclosed amount of cash and fees to Searle.

Prior to the agreement, Searle had already begun clinical trials in Japan using interferon for viral infections. Now both the companies hope to start the production within eight to ten months.

● **Mass production of interferon:** Researchers working in Hayashibara Biochemical Laboratories, Okayama City, Japan, have suceeded in mass production of interferon. They achieved this breakthrough by isolating human cells that multiply in a hamster to produce interferon. The amount of interferon that a hamster yields equals to that of 100 human donors. About 3 years ago, the research team cultivated human leukemic cells that produce interferon, and transplanted them subcutaneously into hamsters within 24 hours of their birth. An immunity inhibitor was injected to hamsters to prevent the cells from being rejected. In 3 to 4 weeks time the lymphoblasts grow to about the same weight as that of hamster (20 to 30 gm). Using the multiplied cells, the team was able to extract 20 to 40 million units of interferon per hamster. This enabled mass production of interferon without making use of large amount of human blood.

The treatment of cancer or chronic hepatitis usually requires dosages of 3 to 10 million units of interferon. Thus using human blood as raw material for interferon production, the cost of the treatment comes out to more than Rs. 3.30 lakhs/month. But the hamster technique will drastically reduce the cost of treatment which will be anywhere near Rs. 30-35/month. Dr. Y. Nagano and his co-workers are studying the efficacy of mass produced interferon by administering it to cancer patients. However, it will take another 2 to 3 years to establish its clinical utility.

Chronotherapy: A potential therapeutic system

The life of all living beings moves in rhythms or cycles and there are daily, weekly, monthly and annual rhythms. Chronopharmacology is the study of the effects of such rhythms on drug therapy. The administration of drugs at regular timed intervals may not be optimal because these times may not synchronise with biological rhythms. The characteristics of rhythms (like temperature) can be measured by fitting frequent determinations of the characteristics to a cosine curve using a computer. This approach holds good when changes in characteristics are approximately sinusoidal rather than linear. Different characteristics can be used as markers for the various rhythms. For different diseases it may be necessary to change markers. Once the appropriate rhythm for a particular patient is established, the treatment should be scheduled in that way only. Care should be taken when the rhythm changes with treatment. Chronotherapy is most useful for patients who take high risk or high cost drugs and for those with a high-risk disease like cancer.

Inpharma, No. **226,** 3 (1 March 80)

Protacine—a new drug for arthritis

Protacine (CR604; Rotta, Italy), is a new powerful non-steroidal anti-inflammatory drug with analgesic and antipyretic activity and has fewer effects on the cardiovascular, respiratory, digestive and central nervous systems. In a double-blind trial 20 patients with hip arthritis were given either 150 mg protacine or 50 mg indomethacin *tid* orally for 10 days, and 20 more patients with other inflammatory conditions were given either 150 mg protacine or 200 mg oxyphenbutazone *tid* orally for 18 days.

All 3 drugs significantly reduced pain but there were no differences between treatments. Protacine produced some significant improvements in hip mobility, but not knee, while indomethacin produced no significant changes in either. Protacine was well tolerated with only one case of mild gastric upset.

Inpharma, No. **226,** 6 (1 March 80)

Benzodiazepine associated risks

Dr. Gerard Vaughan, the UK Health Minister told the British Parliament that an expert committee which conducted a comprehensive study on all aspects of the clinical use of benzodiazepines, including diazepam, had found their addiction potential generally as low. However, on withdrawing benzodiazepine treatment suddenly, adverse effects like apprehension, insomnia, tremors and nausea appeared. These effects were usually seen in cases which had received high doses particularly over long periods.

Scrip, No. **471,** 2 (15 March 80)

Infertile women conceive with levodopa

Seventeen women who had failed to conceive for 4 or more years when given low doses of levodopa (125 mg/day) plus haloperidol (0.3 mg/day) conceived within 2 months of attempted conception. Medication was stopped 15 days after the first missed period. Eleven normal babies have been delivered and 5 normal pregnancies are in progress. There was one spontaneous abortion. All patients had regular menstrual periods, although 5 had high serum prolactin levels.

Inpharma, No. **226,** 11 (1 March 80)

Problem with Vitamin K-type coagulants

Vitamin K-type coagulants have been found to have bioequivalence problem. US Food and Drug Administration has well documented data which suggests actual bioequivalence differences in oral formulations of these coagulants' currently marketed brands. This will require human *in vivo* testing.

PMA Newsletter, **22,** 8 (24 March 80)

Nodolol: a β-blocker with a long half-life

Nodolol ('Corgard', Squibb) is a non-selective β-adrenoceptor blocking agent which lacks membrane stabilising effect and intrinsic sympathomimetic activity. It has about 2-4 times the potency of propranolol and is absorbed rapidly (about 30% of an oral dose). It is not metabolised and is excreted unchanged in the urine (70%) and bile (30%). It has the longest half-life (17-23 hours) of any β-blocker available at present. It resembles propranolol pharmacodynamically, but is less effective in suppressing digoxin-induced arrhythmias and has 5 times more duration of β-blockade. Unlike other β-blockers it increases renal blood flow. In hypertension it has proved safe and effective.

Its long half-life allows a once-a-day dosage schedule, which in general tends to improve patient compliance compared with multiple daily dosing. However, for hypertension this long half-life may not be of much advantage since the antihypertensive effects of other β-blockers outlast detectable blood levels and frequent dosing is unnecessary for these too. Also for the treatment of angina and arrhythmias its effect is not well established.

Inpharma No. **227,** 3 (8 March 80)

Cefotaxime a cure in acute gonorrhoea

A young women was successfully cured of acute gonorrhoea caused by a β-lactamase producing strain of *Neisseria gonorrhoeae*, by cefotaxime. She was first treated with *im* Kanamycin (2g) but soon became rainfected. After a 7-day course of oral tetracycline (1g/day) and 7 days of oral erythromycin (1g/day), cervical and urethral swabs yielded β-lactamase producing strain of *N. gonorrhoeae*. She was given *im* cefotaxime (1g in each buttock) and 49 days later she was completely cured of gonorrhoea. The minimum inhibitory concentration of cefotaxime for this strain of *N. gonorrhoeae* was 0.015 mg/L.

Inpharma, No. **227**, 11 (8 March 80)

Drugs excreted in human breast milk

In mothers' breast-feeding their baby the daily milk production may range between 400-900 ml. The data on excretion of most drugs in breast milk are so scanty that dosing via milk and the risk to an infant remain speculative. The pH of the milk appears to be within 6.35-7.65 range and any variation in it can influence drug excretion. Drug excretion is also influenced by milk composition and yield, blood flow to mammary tissue, drug binding to plasma protein and milk protein, drug ionisation and lipid solubility.

Once inside the alveolar cells of the breast, drug may be metabolised (e.g. sulphanilamide) by mammary tissue, but if already metabolised, the metabolite is excreted into the milk fróm the plasma. The drug may progress to the alveolar lumen, or It may possibly be partially reabsorbed. Knowledge of the pharmacokinetics of the drug can help in the prediction of drug excretion and calculation of the dose received by the infant.

The drugs which are contraindicated in nursing mothers include chloramphenicol, phenytoin, ^{131}I, phenobarbitone and thiouracil as an infant would receive these in amounts $>1\%$ of the maternal dose. Antithyroid drugs, lithium, anticancers drugs, metronidazole, tetracyclines and ergots also fall in the category of these prescribed drugs.

Use of nalidixic acid, sulphonamides antimalarials, isoniazid, meprobamate, primidone, atropine, caffeine, chronic salicylate, diphenoxylate, loperamide and cimetidine should be done with caution.

Inpharma, No. **227,** 16 (8 March 80)

M. leprae resistant to dapsone

According to the Director, School of Tropical Medicine, Calcutta, dapsone resistant *Mycobacterium leprae* has been observed. This observation similar to high incidence of bacterial resistance observed in tuberculosis therapy.

Drug trials and their effectiveness

A trial is 'controlled' when the results of the main treatment are compared with those of another treatment. 'Randomised' trial is that controlled trial which additionally involves statistical assignment of the different treatments to each patients. Whereas in a randomised trial the comparisons between treatments are always concurrent, the non-randomised studies permit historical comparison with the treatments used in the past. But present changed diagnostic criteria and refined therapy make these comparisons not on identical bases. A 'random' trial gives each patient an equal chance of receiving any of the treatments being compared and this gives a valid statistical analysis of the trial but the trial is not feasible when a number of different treatments require evaluation or the new treatment is distinctly superior or inferior to the previous one.

Double-blind trials make subjective evaluation of parameters such as pain relief, improvement in physical function or work capacity.

A 'Placebo' is required for the valid comparison of therapy and an untreated patient does not develop the 'Placebo effect'. This effect is valuable when patients may have a wide spectrum of clinical symptoms making the effects of an active agent difficult to distinguish from placebo. The use of placebo is a necessity for scientific fairness in comparison.

Inpharma, No. **228,** 4 (15 March 80)

Certain vaginal creams not effective

At a joint meeting of the US FDA's Anti-infective and Topical Drugs Advisory Committee and Fertility and Maternal Health Advisory Committee it was reported that vaginal creams containing sulfanilamide (AVC cream, Merrell; Vagitrol cream, Syntex) or sulfisoxazole (Gantrisin cream, Roche) are not effective in treating vaginitis caused by *Candida albicans*, *Trichomonas vaginalis* and *Haemophilus vaginalis*.

FDA says that although reports in the medical literature warn since 1940's of the toxicity of sulfas and question their efficacy in curing vaginitis, the clinical use of these creams has persisted largely due to the early symptomatic relief they appear to provide. However, even the use of bland cream or the base alone without the sulfas can provide relief, according to FDA. Effective alternative treatments recommended by the FDA include intravaginal miconazole or clotrimazole or nystatin for vulvovaginal candidiasis, oral metronidazole for trichomoniasis, and oral ampicillin, tetracycline or other antibiotics for *Haemophilus vaginalis* vaginitis.

Scrip, No. **471,** 13 (15 March 80)

Midazolam : *iv* anaesthetic with short half-life

Midazolam maleates (benzodiazepine) was given 10.5 mg over 15 minutes and 15.5 mg over 3.75 hours *iv* to five subjects to achieve steady-state serum levels. The drug was completely metabolised and 40% of the 1-hydroxymethyl analogue was excreted in the urine in 12 hours and 50% by 24 hours. The drug caused no pain and showed no venous thrombosis over 7-10 days when volunteers were given 5-10 mg *iv.* Compared to diazepam, midazolam showed rapid disappearance from the blood and almost no 'second peak' effect. After 10 mg, recovery times (response to command) were 0-42 minutes and patients were fully awake and standing at 80-180 minutes. This suggests a potency about double that of diazepam but the degree of amnesia same as for diazepam.

Inpharma, No. **228,** 9 (15 March 80)

Mexiletine—an antiarrhythmic—to be investigated in USA

A promising drug for the treatment of arrhythmias is to be investigated in USA. Known as Mexiletine it is currently used in UK for the treatment of arrhyththmia to prevent sudden deaths. Mexiletine has been developed from a group of drugs having both β-blocking and anticonvulsant properties but it has no β-blocking effect and was labelled as an antiepileptic. It suppresses arrhythmias in animals, is effective like lignocaine (lidocaine) in inducing local anaesthesia and possesses antiarrhythmic activity similar to quinidine and procainamide. It can be given intravenously, intramuscularly and orally. Bioavailability is 75-80% and absorption is rapid. It has a long elimination half-life and can suppress arrhythmias from myocardial infarction, cardiac surgery, ischaemic heart disease and digitalis toxicity. In long term treatment, late toxicity (as seen with procainamide) is rare. Although its therapeutic margin is narrow its mode of action different from other antiarrhythmics makes it often work, and individualisation of dose usually achieves good control without toxicity.

Inpharma, No. **229,** 3 (22 March 80)

New compound enhances frusemide diuresis

SB 7505 (Simes, Italy) is a dopamine analogue having positive inotropic effect which increases renal blood flow thereby inducing diuresis. In a case study, 7 healthy subjects were given 25 mg frusemide compared to two 50 mg doses of SB 7505, 12 hours apart, and 25 mg frusemide was given with the second dose of SB 7505. The first dose was to obtain a pharmacodynamic effect as SB 7505 works slowly.

Frusemide increased diuresis by 95% while SB 7505 and frusemide in combination increased diuresis by 162%. Sodium excretion increased by 53% and 87% and potassium by 21% and 57% respectively in single or combination administration.

There were no variations in other electrolytes (except Na : K ratio which increased only with frusemide), blood pressure or heart rate.

Inpharma, No. **229,** 8 (22 March 80)

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REGULATORY NEWS

Equity dilution of Drug MNC's: Ministry's recommendations questioned

Reserve Bank of India has rejected as 'unacceptable' the recommendations of Union Ministry of Petroleum, Chemicals and Fertilisers that all multinational drug companies, except two, should be treated as high technology units. The Expert Committee of the Ministry had only identified the nature of technology for certain items as high technology. The FERA Committee of the Reserve Bank has expressed its surprise at the Ministry's stand that equity holding should be determined as per para 17 of the drug policy.

The drug policy of Government stipulates that equity holding has to be in step with the quantum of sophisticated technology, and then, all drug companies will have to be treated at par and will have to be allowed to retain majority equity. Further the FERA committee says, that if a company is using high technology for 80 per cent of its products and another is using for only one or two items then to equate both will be a violation of the Foreign Exchange Regulation Act. Contrary to Ministry's report that all bulk drugs could be treated as high technology items, the FERA committee pointed out that only high technology bulk drugs and formulations based on them could be treated as core sector. Of the 24 companies having equity more than 51 per cent, 14 have equity exceeding 74 per cent, and 10 have between 51 and 74 per cent. So, according to Reserve Bank of India, most of these drug units will have to bring down their equity substantially and its FERA committee will decide about the holding.

Status quo to be maintained in Hong Kong patent system

Hong Kong patents working party has decided that no change is needed in the existing system of patent registration in the country. At present a patent registered in UK can automatically be registered in Hong Kong, but it is not possible to determine whether a patent holder intends to extend the patent to Hong Kong and for how long. And also, when a patent is not renewed in UK, a research has to be made in UK to know of its status in Hong Kong. It was suggested that the five year period, within which a patent must be registered in Hong Kong, should be reduced and a system of renewal fees should be introduced in order to eliminate these uncertain elements in the current system. But now since the Hong Kong patents working party has decided of no change in the existing system, a legal sub-committee has been formed to see what amendments, if any, should be made but question of compulsory licences and crown use is not to be investigated.

Scrip, No. **464,** 14 (20 Feb. 80)

Gulf countries for centralised purchases

Health Ministers of the Gulf countries at a meeting in Baghdad have decided that by 1982, 50% of their pharmaceutical requirements should be bought via a central purchasing department. It was also suggested that the purchase of hospital equipment should be centralised.

Scrip, No. **465,** 11 (23 Feb. 80)

Registration and import of new medicines banned in Lebanon

According to an order of the Labanese Minister of Health, the registration and import of new medicines has been banned with immediate effect. But the medicines which are of a unique type and have no equal or which are specifically intended for incurable diseases are excluded from this order. However, the registration and import of even these medicines will be subject to the endorsement of the Minister of Public Health.

Scrip., No. **469,** 12 (8 March 80)

New Zealand updates GMP code

Based on the Good Manufacturing Practices (GMP) codes of WHO, UK, Canada, Australia and USA, New Zealand has also come up with its own revised "Code of Good Practice for Manufacture and Distribution of Medicine". The revised GMP code covers:

1. Manufacture and distribution of all medicines and medical devices; 2. Cosmetics—in terms of wholesale distribution of medicines and related products; 3. Related products are defined as cosmetic, dentifrice or food for which a therapeutic claim is made; 4. Sterile products—additional requirements for aseptically prepared products, terminally sterilised products, products aseptically filled after bulk sterilization and sterlization by steam, ethylene oxide and radiation; 5. Standard procedures for medicine recalls.

The code has standards for all stages of manufacture and distribution of medicines but has no statutory force. It is not to be taken as interpretation of law and this makes it flexible and interpretable as required for individual cases.

International Drug Regulatory Monitor,
No. **81**, 5 (Feb. 80)

Guidelines for Swedish drug information council

The special working party set up by the Swedish Social Affairs Department to work out activities for the proposed drug information council has submitted the following guidelines relating to the objectives and tasks of the council:

1. The council is an organ for cooperation between representatives of all interests in the drug area, its aims being to increase knowledge of drugs in the community and thus to create the conditions for a better use of medicine.

2. The council is to consider and give its opinion on general questions such as the formulation of objectives in drug information for the general public or professional groups, the definition of areas of responsibility for information givers, the drawing up of ethical rules for drug information, the evaluation of the effects of various methods of information and

the drawing up of recommendations for the evaluation of such methods.

3. The council is to take steps and in general act to see that urgent informational and educational activities are carried out and that developmental, experimental and publication activity takes place in neglected areas. In particular, the council should see that wider and better information gets to the public and the patients; that there is better instruction in the basic training of professionals dealing with drugs; that there is an increase in the amount of problem-oriented and non-company drug information; that local drug information is increased and organised; and that awareness of costs in drug matters is highlighted. The council should see that these activities are co-ordinated with informational activities in the health care and social system in general.

4. The council should produce information or handle education on its own initiative if other organs are not available or if special skill is otherwise needed.

There are some guidelines relating to the duties of the members in the council. All these guidelines and the working party's report are now being considered by the Social Affairs Ministry.

Scrip., No. **470**, 2 (12 March 80)

US FDA recalls Ticrynafen

Ticrynafen, a drug which was reported to be a combination of anti-hypertensive, diuretic and uricosuric properties, has been recalled from the US market by Food and Drug Administration following the reports that drug induces jaundice in patients. Ticrynafen's clinical trials were undergoing in India also and now these have been suspended pending detailed examination of the reported side effects, especially as to whether jaundice was Ticrynafen related.

Propoxyphene section of US Pharmacopoeia needs revision

The US Food and Drug Administration has asked the US Pharmacopoeia to revise the propoxyphene section under its "USP Dispensing Information" to bring it in line with the FDA approved voluntary patient package inserts developed by Eli Lilly & Co., for Darvon products. FDA sources point out that the USP does not reflect the Lilly-PPI cautions about possible dependence, death due to overdose and the additive effects of concomitant use of alcohol and other drugs in its "advise for the patient" section.

Scrip., No. **470**, 8 (12 March 80)

US FDA begins dispensing-level quality survey

The US Food and Drug Administration has started its first dispensing-level survey of drug product stability. The first drug to be sampled is "digoxin", chosen because of recent data indicating that the tablets develop dissolution problems during storage. Some 200 samples will be purchased from hospital pharmacies. Each is to be within 12 months of its labelled expiry date.

The samples will be tested for dissolution performance and the development of degradation toxicity. Some other drugs which may undergo these tests are prednisone, hydrochlorothiazide and furosemide.

Scrip., No. **471,** 11 (15 March 1980)

PMA contests FDA/NDA revision case

Pharmaceutical Manufacturers Association of USA has critisised the US Food and Drug Administration's proposal for the revision of IND/NDA regulations in order to simplify and speed up the process. According to the Association, FDA's "Concept papers" proposing IND/NDA revision could have the opposite effect by demanding even more than what is required at present.

The PMA President said that the FDA proposal asking for details of early clinical studies will increase the burden on both the FDA and the drug sponsorer and will increase rather than reducing the delay. PMA is going to submit its own IND/NDA revision proposals and these will involve FDA to substantially less extent. It will propose a 'local check' backed by government oversight in some key clinical trials.

PMA has also resented the FDA's second concept paper on IND records and reports that the advantages of a certain drug over other members of the same class be stated in IND submissions. PMA has further elaborated its proposals, like (*a*) its support to the use of 'comprehensive summaries' of clinical and pre-clinical data; (*b*) its opposition to any requirement of notifying FDA of 'the mere filing' of an NDA in foreign countries; (*c*) its belief that post-marketing studies and surveillance are separate controls which must be treated differently; and (*d*) its strong opposition for any intended revision of the existing ANDA regulation that include post 1962 new drug products.

Scrip, No. **466**, 8 (27 Feb. 80)

US FDA to update IND/NDA regulations

The United States Food and Drug Administration is proposing to revise its international research IND/NDA regulations. For this it will adopt the 1975 Tokyo revision of the declaration of Helsinki and take into consideration another document entitled "Investigational and New Drug Regulations—Revisions".

The Tokyo revision of World Medical Assembly's Helsinki Declaration states: "The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should by transmitted to a specially appointed independent committee for consideration, comment and guidance".

On the above basis FDA will highlight the need for ethical monitoring of medical research involving human subjects and will develop mechanisms in the new IND/NDA regulations to enhance international participation on drug regulatory evaluations and decisions. The revision will harmonise US drug regulations and technical requirements with those of WHO, EEC, Pan American Health Organisation and others.

International Drug Regulatory Monitor, No. **82**, 1 (March 80)

Drug policy in France

Some important measures have been taken as a part of "New Scientific Policy for Drugs" in France. According to Mr. Jacques Barrot, the French Health Minister, the measures are:

1. A Drug Innovation Committee will advise the Health Minister. The

committee will have representatives from all ministries concerned with drugs, the chairman of all committees dealing with drugs and directors of state research institutes concerned with drugs.

2. State research organisations will set up information and liaison offices to inform pharmaceutical manufacturers of their research programmes and capabilities.

3. Five new clinical pharmacology departments will be established in the current year. The teaching of Pharmacology and its clinical aspect will be developed further. Ethical committees will be set up in state hospitals to approve and monitor clinical trials.

4. Existing contract toxicological testing laboratories will be expanded and new laboratories will be set up.

5. Two representatives of the industry will be appointed to the marketing approval committee. The committee will keep in touch with applicants throughout the processing of an application.

6. A new campaign to promote the good usage of drugs will be undertaken. Doctors will not be allowed to prescribe for more than one month's treatment.

Scrip, No. **471,** 4 (15 March 80)

New drug pricing system in France

Mr. Jacques Barrot has announced a new pricing system for reimbursable products which will be effective within a few months. The policy will be operative as under.

1. The Economic Ministry will no longer be responsible for fixing drug prices. Manufacturers will be allowed to determine the prices of their new drugs freely, but the Health Ministry will continue to be responsible for the reimbursements, but can 'grant or reject' reimbursement applications on the following basis: (*a*) the technical value of the product; (*b*) its current or potential market in France or abroad; (*c*) the budgetary requirements of the insurance scheme.

2. Prices of already marketed products will be controlled by the Health Ministry. They will be granted a general average price increase with a free 'modulation' once or twice a year.

3. The reimbursement committee will become the 'transparency committee'. It will compare the daily dosage costs of new and already marketed products in the various therapeutic categories, and distribute price comparison cards to doctors. It will monitor drug consumption and see that pack sizes meet therapeutic needs. The committee will also look at reimbursable rates and advise the ministry on whether to exclude a new product from the reimbursement list if its price was out of line with its therapeutic value.

Scrip, No. **469,** 4 (8 March 80)

Eight drugs placed under international curbs

World Health Organisation has recommended placement of three narcotics and five psychotropic substances under international control as they pose a danger to public health. The drugs are dependence-producing with a capacity to affect the mind.

U. N. Commission on Narcotic Drugs which recently had a session in Vienna has already acted upon these recommendations. The list includes a synthetic drug phencyclidine, commonly known as Angel Dust, which is used exclusively by veterinarians for quietening animals. The abuse of this drug among North American school children is quite rampant. Other psychotropic drugs are phencyclidine analogues and mechloqualone. The narcotics drugs recommended for control are sufentanil, tilidine and dextropropoxphene. They produce "morphine" or "opiate" type effects in users.

Assessment of drugs/medical devices before approval

The National Centre for Health Care Technology, a new agency of the US Dapartment of Health, will assess a few of the technologies significant to the areas of health care. The areas of interest are (1) maternal serum alpha-fetoprotein screening for neural tube defects, (2) caesarean sections, (3) coronary bypass surgery, (4) dental radiography, (5) cardiac transplantation and (6) end-stage renal disease in all its aspects.

PMA Newsletter, **22,** 1 (31 March 80)

UN commission for control on several drugs

UN Commission on narcotic drugs has recommended appropriate control measure on sufentanil, tilidine, dextropropoxyphene, phencyclidine and mecloqualone, under 1961 Convention on Narcotic Drugs and 1971 Convention on Psychotropic substances.

Sufentanil (Janssen) is an analgesic ten times more potent than fentanyl and has been found to have morphine-like effects. It is potentially attractive for illicit traffic. Although data on its dependence ability or actual abuse are lacking, it is recommended to be put under Schedule I (abuse potential) and IV (high potency) of the Narcotics convention.

Tilidine (Valoron, Goedecke, Centrac, Parke-Davis) is recommended to be placed under Schedule I of the Narcotics convention as it has been found to produce opiate like effects and its reported abuse and illicit traffic is also on an increase.

Dextropropoxyphene (Darvon, Lilly; etc) is an effective analgesic for mild to moderate pain with abuse potential not greater than codeine. It is recommended for Schedule II as US and Canada have reported deaths associated with this drug (usually in combination with alcohol or depressant drugs) and also many countries have already subjected it to Narcotics controls. Phencyclidine (Sernyl, Parke-Davis) is maintained status quo as a Schedule II drug, as no significant abuse of this drug was found outside North America. Three more potent phencyclidine analogues are also placed under Schedule I of the Psychotropic Convention because of their strong abuse potential.

Mecloqualone (Nubarene, Diamant/ Roussel Uclaf) is a hypnotic sedative related to methaqualone, which is under Schedule II of the Psychotropic Convention. Mecloqualone is therefore also recommended under Schedule II as no evidence for a therapeutic use of this drug was found, which cannot be met with other widely used and less abuse potential drugs.

Scrip, No. **470,** 9 (12 March 80)

US FDA proposal for carbonic anhydrase inhibitors

The US Food and Drug Administration has proposed that oral carbonic anhydrase inhibitors such as acetazolamide, dichlorphenamide, ethoxazolamide and methazolamide should be subjected to a bioequivalence requirement because of well-documented differences between marketed products. The proposal would require *in-vivo* human tests in addition to dissolution tests.

Although the above mentioned drugs were developed as diuretics, the FDA says that their major usefulness is "in treating primary glaucoma, the acute phase of secondary glaucoma and pre-operatively in acute angle-closure glaucoma to lower intraocular pressure before surgery". Acetazolamide 250 mg tablets (Diamox, Lederle) are given as the example of bioequivalence in the proposal. Two ANDA's submitted to FDA by other manufacturers' indicated that one brand was 6.5 times faster in absorption than Diamox, the FDA proposal says. In addition, the tests show significant lot-to-lot variation in Diamox, since reformulated. Diamox is the reference product for the proposed bioequivalence requirements

Scrip, No. **470,** 8 (12 March 80)

Karnataka State Drugs Control Department

(Monthly Report: January 1980)

During this month, the Drugs Control Department granted one licence for manufacturing biological drugs, five for non-biological drugs and one for cosmetics manufacture. Similarly 378,525 and 8 establishments were given licences to sell biological, non-biological and homoeopathy drugs respectively.

The department carried out inspections of 11 manufacturing, 381 sales and 40 hospital premises; 46 inspections were carried out under Drugs (Prices Control) Order. Two contraventions were detected at sales establishment. Substandard drugs worth Rs. 672/- were destroyed.

Drugs sales establishment were under a fairly rough weather as 2 licences were suspended, 38 cancelled, 35 invalidated and 11 licencees were warned. One prosecution was launched under Drugs and Cosmetics Act. Three contraventions were detected out of 375 advertisements scanned under Drugs & Magic remedies (Objectionable advertisement) Act, of which warning was issued in one case.

UK Medicines Commission approves new names

The UK Medicines Commission has issued the sixth supplement to the list of British Approved Names. The order effective from March 1st, 1980 includes the following compounds:—

Generic Names	Synonym	Company	Activity
Alprostadil	U-10, 136	Upjohn	Vasodilator
Amiodarone	L-3428	Reckitt & Colman	Antiarrhythmic
Bezafibrate	BM-15, 075 LO-44	MCP Pharmaceuticals	Hypolipaemic
Canrenoic acid	—	MCP Pharmaceuticals	Diuretic
Cotetroxazine	Tetroxoprim + sulfadiazine	Hemuann	Antibacterial
Domperidone	R-33812	Janssen	Antiemetic
Endralazine	BQ-22-708	Sandoz	Antihypertensive
Epimestrol	Org-817	Organon	Oestrogen
Flunarizine	R-14,950	Janssen	Vasodilator
Ketoconazole	R-41,400	Janssen	Systemic antifungal
Lorcainide	R-15,889	Janssen	Antiarrhythmic
Pirquinozol	SQ-13847	Squibb	Antiallergic
Rosaramicin	Sch-14947	Schering-Plough	Antibiotic
Sutilains	Travase	Travenol	Wound debridement
Tamitinol	EMD-21,657	E. Merck	Cerebral disease therapy
Tiaprofenic acid	RV-15,060	Roussel	Anti-inflammatory
Tixocortol	JO-1016	Jouveinal	Corticosteroid
Urofollitrophin	—	Serono	Follicle-stimulating hormone

Scrip, No. **469,** 14 (8 March 80)

FDA approves many drugs for OTC use

US Food and Drug Administration's OTC Advisory Review Panel has approved thirty drugs available prior to December 79 as prescription-only medicines, as safe for over-the-counter sale to consumers. Five ingredients which were already allowed in non-prescription medicines have been termed safe in doses previously limited to prescription-only drugs. Of these 35 recommendations, FDA has agreed to 13, disagreed with nine and about the rest 13 the decision is pending. The status of the recommendation is as shown:

Indication	Active ingredient
A. *Recommendations agreed to by FDA*	
Anti-inflammatory	Hydrocortisone 0.25-0.5%
Antipruritic	Hydrocortisone acetate 0.25-0.5%
Antihistamine	Brompheniramine maleate (oral) 4 mg/4-6 hrs Chlorpheniramine maleate (oral) 4 mg/4-6 hrs Diphenhydramine hydrochloride (Oral) 25-50 mg/4-6 hrs
Bronchodilator	Methoxyphenamine hydrochloride (oral) 100 mg/4-6 hrs
Nasal decongestant	Oxymetazoline hydrochloride (topical 0.05% aqueous solution) Pseudoephedrine hydrochloride (oral) 60 mg/4 hrs Pseudoephedrine sulphate (oral). Xylometazoline hydrochloride (topical) 0.1% aqueous solution
Antidiarrhoeals	Opiates (only in combination)
Antiemetic	Meclizine hydrochloride (25-50 mg once daily)
Night-time sleep aid	Doxylamine succinate
B. *Recommendations disagreed by FDA*	
Antihistamine	Doxylamine succinate (oral) 7.5-12.5 mg/4-6 hrs Bromethazine hydrochloride (oral) 6.25-12.5 mg/8-12 hrs

Indication	Active ingredient
Antitussive	Diphenhydramine hydrochloride (oral) 25 mg/4 hrs
Bronchodilator	Aminophylline Theophylline anhydrous Theophylline calcium salicylate Theophylline sodium glycinate (oral) theophylline equivalent 100-200 mg/6 hrs
Night time sleep aid	Diphenhydramine hydrochloride Phenyltoloxamine dihydrogen citrate
C. Recommendations pending with FDA	
Anthelmintic	Pyrantel pamoate
Treatment of minor vaginal irritations	Sodium propionate Calcium propionate
Vasoconstrictors	Epinephrine hydrochloride Phenylephrine hydrochloride Ephedrine sulphate (all in aq. solution)
Dental rinses	Sodium fluoride rinse (0.05%) Stannous fluoride rinse (0.1%) Stannous fluoride gel (0.4%) Acridulated phosphate fluoride rinse (0.02% fluoride)
Toothache relief agent	Eugenol (85-87%) Butacaine sulphate (4% ointment)
Tooth desensitizing agent	Potassium nitrate 5%

Scrip, No. **466,** 9 (26 Feb. 80)

PRODUCTION/IMPORT FIGURES

ESSENTIAL BULK DRUG PRODUCTION DURING APRIL-DECEMBER, 1979

Name of Bulk Drug	Production during April-December 1979
I. ANTIBIOTICS	
1. Penicillin	241.15 MMU
2. Streptomycin	168.86 Base T
3. Chloramphenicol powder	48.35 T
4. Tetracycline	101.87 T
5. Oxytetracycline	85.39 T
6. Ampicillin	13.09 T*
7. Erythromycin (Estolate/Stearate)	20.93 T
II. SULPHA DRUGS	
1. Sulphadimidine	373.42 T
2. Sulphacetamide	26.99 T
3. Sulphaphenazole	89.52 T
4. Sulphasomidine	193.52 T
5. Phthalyl sulphathiazole	6.48 T
III. VITAMINS	
1. Vitamin A	47.14 MMU
2. Vitamin B_1	41.94 T
3. Vitamin B_2	5.78 T
4. Vitamin B_{12}	84.50 Kg
5. Folic Acid	2.47 T
6. Vitamin C	583.82 T
IV. ANALGESICS, ANTIPYRETICS Etc.	
1. Analgin	273.80 T
2. Aspirin	755.86 T
3. Paracetamol	76.85 T
4. Phenyl butazone	40.38 T
5. Oxyphenyl butazone	16.32 T
6. Codeine and salts	5.72 T

Contd.

Name of the Bulk Drug	Production during April-December 1979
V. CORTICOSTEROIDS	
1. Prednisolone	751.00 Kg
2. Dexamethazone	70.97 Kg
3. Betamethazone	266.06 Kg
VI. ANTI-T. B. DRUGS	
1. PAS and its salts	352.29 T
2. I. N. H.	83.18 T
3. Thiacetazone	9.98 T
VII. ANTIMALARIALS	
1. Chloroquin	33.42 T*
2. Amodiaquin	28.34 T
3. Quinine	3.16 T†
VIII. ANTIDYSENTARY DRUGS	
1. Metronidazole	66.59 T
2. Halogenated oxyquinolines	176.30 T
(*a*) Di-iodo-hydroxyquinolines	9.80 T
(*b*) Iodo-chloro-hydroxyquinolines	127.00 T
(*c*) Intestopan substance	39.50 T
IX. ANTIDIABETICS	
1. Insulin	1122.00 MU
2. Chlorpropamide	6.93 T
3. Glybenclamide	0.35 T
X. C. N. S. STIMULANTS	
1. Caffeine	86.27 T
XI. DIURETICS	
1. Frusemide	3.19 T
XII. ANTIASTHMATICS	
1. Ephedrine	21.53 T
XIII. CARDIOVASCULAR DRUGS	
1. Xanthinol nicotinate	10.64 T
2. Digoxin	4.86 Kg
XIV. ANAESTHETICS	
1. Lignocaine/Xylocaine	5.44 T

Contd.

Name of the Bulk Drug	Production dring April-December 1979
XV. ANTIHELMENTICS	
1. Piperazine and its salts	64.02 T
XVI. ANTIHISTAMINES	
1. Pheniramine maleate	5.04 T
XVII. TRANQUILIZERS AND SEDATIVES	
1. Phenobarbitone	19.97 T
XVIII. ANTIFILARIALS	
1. D. E. C. citrate	16.93 T
XIX. ANTILEPROTICS	
1. D. D. S. (Dapsone)	10.36 T
XX. IMMUNOLOGICAL AGENTS	
1. Triple vaccine	5688.96 Ltr.

* Provisional.

† Excluding Government Quinine Factory, West Bengal.

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BULK DRUG IMPORT FIGURES DURING APRIL 79 TO SEPTEMBER 79

Name of the Bulk Drug	Qty. Imported During April '79 to Sept. '79
I. ANTIBIOTICS	
1. Chloramphenicol	28.0 T
2. Chloramphenicol palmitate	10.0 T
3. Chloramphenicol sodium succinate	2.2 T
4. Tetracycline	68.3 T
5. Doxycycline Hcl.	971.0 Kg
6. Penicillin G. sodium	3592.0 Bu
7. Penicillin G. procaine	5675.0 Bu
8. Ampicillin trihydrate/anhydrous	22.7 T
9. Framycetin sulfate	1.25 T
10. Neomycin sulfate	3.25 T
11. Cephatexin	755.0 Kg
12. Gentamycin	380.0 Kg
13. Cycloerine	1.2 T
14. Rifampicin	564.0 Kg
15. Bacitracin/Bacitracin zinc	25.0 Bu
16. Viomycin	296.0 Bu
II. SULPHA DRUGS	
17. Sulphadiazine	82.0 T
18. Sulphamethoxazole	40.75 T
III. VITAMINS	
19. Vitamin A	13994.0 Bu
20. Vitamin B_1	54.8 T
21. Vitamin B_2	16.0 T
22. Vitamin B_6	26.65 T
23. Vitamin B_{12}	4.7 Kg
24. Folic acid	230.0 Kg
25. Sodium/calcium pantothenates	29.0 T
26. Panthenol	11.4 T
27. Vitamin C	40.5 T
IV. ANALGESICS, ANTIPYRETICS, ANTIRHEUMATICS Etc.	
28. Analgin	100.7 T
29. Oxyphenyl butazone	8.4 T
30. Amidopyrine	52.0 T
31. Dextropropoxyphene	2.16 T
32. Aspirin	157.7 T

Name of Bulk Drug	Qty. Imported During April '79 to Sept. '79
33. Pyrithyldone	8.0 T
34. Propylphenazon	18.0 T
V. CORTICOSTEROIDS	
35. Prednisolone	639.0 Kg
36. Hydrocortisone	167.0 Kg
37. Dexamethazone	94.0 Kg
38. Triamcinolone	36.0 Kg
VI. ANTI-T. B. DRUGS	
39. Ethambutol	58.7 T
40. Pyrazinamide	2.9 T
VII. ANTIMALARIALS	
41. Chloroquin and its salts	50. 4 T
VIII. ANTIDYSENTERY DRUGS	
42. Furazolidone	22.3 T
IX. DIURETICS	
43. Aminophylline	17.5 T
44. Theophylline	47.4 T
45. 7-(2-hydroxyethyl) Theophylline	7.8 T
X. ANTIASTHMATIC DRUGS	
46. Salbutamol	179.0 Kg
47. Ephedrine and salts	4.28 T
XI. CARDIOVASCULAR DRUGS	
48. Methyl dopa	2.0 T
XII. ANTHELMINTICS	
49. Piperazine hexahydrate	70.0 T
50. Thiabendazole	10.0 T
XIII. ANTIHISTAMINIC DRUGS	
51. Tripoledine HCl	160.0 T
52. Chlorpheniramine maleate	12.2 T
XIV. TRANQUILIZERS AND SEDATIVES	
53. Thioridazine	2.49 T

Contd.

Name of Bulk Drug		Qty. Imported During April '79 to Sept. '79
XV.	**ANTIEPILEPTIC DRUGS**	
54.	Phenyl hydantoin and salts	9.7 T
XVI.	**BLOOD PREPARATIONS**	
55.	Polyvinyl pyrolidone	27.7 T
XVII.	**FEMALE SEX HORMONES**	
56.	Norethisterone	86.0 Kg
57.	Lynestrenol	52.0 Kg
XVIII.	**OTHERS**	
58.	Trimethoprim	2.23 T

DRUGS & PHARMACEUTICALS
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INDUSTRIAL LICENCES
ISSUED DURING DECEMBER, 1979

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
1.	Alembic Chemical Works Ltd., Alembic Road, Baroda 390 003.	Baroda	(*i*) Cephalexin capsule	10 lakh capsules	New Article CIL: 266 (79) dated: 5.12.79 LI: 524/79 dated: 31.12.79
			(*ii*) Chlorpropamide	30 tonnes	
			(*iii*) Procaine hydrochloride	30 tonnes (per annum)	
			Bistrepen 1 dose composition: each dose vial contains procaine penicillin G. I. P. 300000 units sodium penicillin G. I. P. 100000 units streptomycin sulphate I. P. equivalent to 0.5 gm of streptomycin base.	90 lakh vials for items 1 & 2 (existing) 400 lakhs (after expn.).	
			Bistrepen 5 dose composition: each 5 dose vial contains procaine penicillin G. I. P. 1500000 units sodium penicillin G. I. P. 500000 units streptomycin sulphate I. P. equivalent to 2.5 gm of streptomycin base.	30 lakhs (after expn.)	
			Bistrepen forte composition: each one dose vial contains procaine penicillin G. I. P. 300000 units sodium penicillin G. I. P. 300000 units streptomycin sulphate I. P. equivalent to 1.0 gm of streptomycin base.	125 lakhs (after expn.) 60 lakhs vials per annum (existing).	

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			Streptomycin 1 gm composition: each vial contains streptomycin sulphate I. P. equivalent to 1.0 gm of streptomycin base.	122 lakhs (after expn.) 60 lakhs (existing)	
			Pencrymycin composition: each vial contains: Sodium penicillin G. I. P. 500000 units streptomycin sulphate I. P. equivalent to 0.5 mg streptomycin base.	5 lakhs vials per annum 40 lakhs (after expansion)	
2.	Bengal Chemicals & Pharmaceuticals Works Ltd., 164, Maniktala Main Road, Calcutta 700054.	Calcutta	Doxycycline	5 tonnes per annum	New Article LI: 416 (79) dated: 7.12.79
			Primaquine tablets B. P. 7.5 mg	1 crores Nos	
			Tetramisole HCl tablets 50 mg	10 lakh Nos	
			Tetramisole HCl tablets 50 mg	2 lakh Nos	CIL: 281 (79) dated: 21.12.79
			Rifampicin capsules 150 mg	10 lakhs Nos	
			Ampicillin capsules I. P. 250 mg	20 lakh Nos	
			Electrolyte powder oral hydration salts (WHO specification)	200 tonnes	
			Mannitol injection B. P.	40,000 liters	
3.	Cadila Laboratories, 244 Ghodasar, Maninagar, Ahmedabad 750 008.	Ankleshwar, Distt. Bharuch (Gujarat)	Dexamethasone and its salts *viz*: Dexamethasone acetate, Dexamethasone sodium phosphate, Dexamethasone valerate	400 Kgs	New Article LI: 517 (79) dated: 31.12.79

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			Betamethasone and its salts *viz*: Betamethasone benzoate, Bethamethasone propionate, Betamethasone sodium phosphate, Betamethasone valerate, Betamethasone valerate acetate	200 Kg	
4.	Shri C. G. Amin, Alembic Chemical Works Co. Ltd., Alembic Road, Baroda 390 003.	Baroda	Alcyclin paediatric drops Composition: Tetracycline base	1200 Lts (per annum) 6800 Lts (After expn)	Substantial expansion LI: 523 (79) dated: 31.12.79
			Algesin tablets composition: Vitamin 'C', Phenylbutazone salicylamide	25 lakhs (per annum) 775 lakhs (after expn)	
			Ephodrox N capsules composition: Chlorpheniramine maleate, Ephedrine HCl, Noscapine base	50 lakhs (per annum) 650 lakhs (after expn)	
			Vikoryl tablets composition: Phenylephrine HCl Chlorpheniramine maleate, N acetyl para amino phenol, Salicylamide	100 lakhs (per annum) 600 lakhs (after expn)	
5.	Fairdeal Corporation Ltd., 142-48, S. V. Road, Jogeshwari, Bombay 400 060.	Roha (Maharashtra)	*Bulk Drugs:* Iothalamic acid B. P. (including its salts)	5 tonnes (per annum)	New Article LI: 476 (79) dated: 31.12.79
			Iopanoic acid B. P. (including its salts)	5 tonnes (per annum)	

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			Formulations: Iothalamate sodium injection (formulation) Iothalamate mugulmine injection Iopanoic acid B.P. tablets (formulation)	Corresponding to 70% production of bulk drugs	
6.	Gujarat Industrial Investment Corporation Ltd., 4th floor, Mistry Chambers, Khanpur, Ahmedabad 380001.	Ankleshwar Distt. Bharuch (Gujarat)	Salicylic acid Aspirin(active ingredient) Aspirin tablets	500 tonnes 300 tonnes 50 tonnes	New Unit LI: 514 (79) dated: 31.12.79
7.	Hindustan Antibiotics Ltd., Pimpri, Pune 411018.	Teh. Haveli Distt. Pune	Ampicillin and semi-synthetic penicillin	5 tonnes (existing) 35 tonnes (after expn)	Substantial Expansion CIL: 271 (79) dated: 14.12.79
			(*i*) Piperazine adipate tablets 300 mg	18 lakh nos	New Article CIL: 279 (79) dated: 21.12.79 CIL: 278 (79) dated: 21.12.79
			(*ii*) Chlorpromazine hydrochloride tablets 25 mg	9 lakh nos	
			(*iii*) Aminophylline tablet 100 mg	18 lakh nos	
			(*iv*) Mebendazole tablet 100 mg	30 lakh nos	
			(*v*) Folic acid tablet 5 mg	360 lakh nos	
			(*vi*) PAS sodium tablet 500 mg	38 lakh nos	
			(*vii*) INH tablet 150 mg	190 lakh nos	
			(*viii*) INH tablet 100 mg	85 lakh nos	
			(*ix*) Analgin tablet 500 mg	108 lakh nos	

Sl No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			(*x*) Sulphadimidine tablet 500 mg	18 lakh nos	
			(*xi*) Ethambutol tablet 100 mg	45 lakh nos	
			(*xii*) Metronidazole tablet 100 mg	41 lakh nos	
			(*xiii*) Metronidazole tablet 200 mg	62 lakh nos	
			(*xiv*) Amoxycillin capsule 200 mg	58 lakh nos	
			(*xv*) Cloxacillin capsule 250 mg	30 lakh nos	
			(*xvi*) Sulphacetamide 300 mg/ml (10 ml bottle)	25 lakh bottles	
			(*xvii*) Sulphacetamide 100 mg/ml (10 ml bottle)	25 lakh bottles	
			(*xviii*) Piperazine citrate syrup (450 ml bottle)	2.5 lakh bottles	
			(*xix*) Theophylline syrup 110 ml bottle	8.5 lakh bottles	
			(*xx*) Oxytetracycline animal formula 25 gm packet	2.00 lakh packets	
			(*xxi*) Oxytetracycline egg formula 40 gm packet	2.00 lakh packets	
			(*xxii*) Streptopenicillin veterinary injection base 2.5 g streptomycin procaine penicillin sodium penicillin	2.00 lakhs packets	
			(*xxiii*) Penicillin veterinary injection procaine penicillin sodium penicillin	2.00 lakhs	
			(*xxiv*) Sulphadimidine tablets 5 g	3.50 lakhs	
			(*xxi*) Oxytetracycline tablets 0.5 g	72.00 lakhs	

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			(*xxvi*) Antibiotic infusion for mastitis 10 ml tubes erythromycin, prednisolone, neomycin	2.40 lakhs	
			(*xxvii*) Piperazine hexahydrate liquid form 100 ml bottles	0.8 lakhs	
			(*xxviii*) Piperazine hexahydrate liquid form 500 ml bottles	0.3 lakhs	
			(*xxix*) Piperazine hexahydrate liquid form 4.5 litres bottles	0.4 lakhs	
			(*xxx*) Phenothiazine powder 1/2 kg, 1 kg pkts	2.0 lakhs	
			(*xxxi*) Quinapyramine 2.5 g vials	2.0 lakhs	
			(*xxxii*) Dichlorphen tablet 0.5 g	2.0 lakhs	
8.	Maharashtra Antibiotics and Pharmaceuticals Ltd., C/o Hindustan Antibiotic Ltd., Pimpri, Pune 411018.	Teh. Higne, Distt. Nagpur (Maharashtra)	(1) Vitamin C Injection 1 ml (110 mg/ml)	20 lakh ampoules	New Unit
			(2) Vitamin C Injection 2 ml (100 mg/ml)	10 lakh ampoules	
			(3) Vitamin C Injection 1 ml 500 mg	3 lakh ampoules	
			(4) Gentamycin Injection 2 ml vial (40 mg/ml)	10 lakh	
			(5) Kanamycin Injection 0.5 gm per vial 2 ml	3 lakh	
			(6) Kanamycin Injection 1 gm per vial 2 ml	3 lakh	
			(7) Erythromycin Injection 2 ml	38.5 lakh ampoules	
			(8) Ampicillin capsule 250 mg	38 lakh	
			(9) Chloramphenicol capsule 250 mg	10 lakh	

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			(10) Rifampicin capsule 50 mg	10 lakh	
			(11) Cloxacillin capsule 250 mg	10 lakh	
			(12) Amoxycillin capsule 200 mg	20 lakh	
			(13) Doxycycline capsule 100 mg	50 lakh	
			(14) Penicillin V 125 mg	15 lakh tablets	
			(15) Penicillin V 250 mg	5 lakh tablets	
			(16) Vitamin C 100 mg	700 lakh tablets	
			(17) Vitamin C 500 mg	100 lakh tablets	
			(18) Erythromycin 250 mg	50 lakh tablets	
			(19) Neomycin 500 mg	7 lakh tablets	
			(20) Folic acid 5 mg	800 lakh tablets	
			(21) PAS Sodium 500	30 lakh tablets	
			(22) INH 50 mg	150 lakh tablets	
			(23) INH 100 mg	80 lakh tablets	
			(24) Analgin 500 mg	44 lakh tablets	
			(25) Sulphadimidine 500 mg	40 lakh tablets	
			(26) Piperazine adipate 300 mg	40 lakh tablets	
			(27) Ethambutol 200 mg	100 lakh tablets	
			(28) Chloroquin phosphate 250 mg	150 lakh tablets	
			(29) Chloropromazine HCl 25 mg	15 lakh tablets	
			(30) Metromidazole 20 mg	30 lakh tablets	
			(31) Metromidazole 100 mg	10 lakh tablets	
			(32) Aminophylline 100 mg	40 lakh tablets	
			(33) Digisine diastase enzyme 200 mg	40 lakh tablets	

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			(34) Multivitamin 500 mg	25 lakh tablets	
			(35) Antacid tablets 1 gm	71 lakh	
			(36) Antiasthmatic 250 mg	25 lakh tablets	
			(37) Rifampicin + INH 150 mg	1 lakh tablets	
			(38) Ampicillin + probenecid	1 lakh tablets	
			(39) Mebendazole 100 mg	10 lakh tablets	
			(40) Rifampicin 150 mg	1 lakh tablets	
			(41) Streptopenicillin 1/2 gm (Injection)	20 lakh vials	
			(42) Fortified procaine penicillin	20 lakhs vials	
			(43) Streptomycin sulphate 1 g base	170 lakh vials	New Unit CIL: 272 (79) dated: 14.12.79
			(44) Streptomycin sulphate 0.75 g base	10 lakh vials	
			(45) Sodium ampicillin 0.5 g base	30 lakh vials	
			(46) Sodium ampicillin 1 g base	30 lakh vials	
9.	Raptakos, Brett & Co. Ltd., 47, Dr. Annie Besant Road, Worli, Bombay 400 025.	Roha Distt. Colaba (Maharashtra)	(*i*) Tinidazole (*ii*) Mebendazole	3 tonnes 6 tonnes	New Article LI: 479 (79) dated: 31.12.79
10.	Searle (India) Ltd., Ralli House, P. O. Box No. 166, 21, Raveline Street, Bombay 400 001.	Ankleshwar Distt. Bharuch (Gujarat)	(*i*) Norpace Chemical (disepe-ramide phosphate and its formulation)	1000 Kg (per annum)	New Article LI: 470 (79) dated: 31.12.79
11.	Standard Pharmaceuticals Ltd., 24, Park Street, Calcutta 700 015.	Serampore Distt. Hooghly (W. Bengal)	(*i*) Tetramisole (bulk drug)	1 tonnes (per annum)	New Article LI: 506 (79) dated: 31.12.79
			(*ii*) Tetramisole tablets	500 kg in terms of the bulk drug	

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
12.	Suhrid Geigy Ltd.. Post Box No. 48, Wadi Wadi, Baroda.	Ranoli Distt. Baroda (Gujarat)	Clonidine hydrochloride	50 kg per annum	New Article CIL: 288 (79) dated: 26.12.79
			(*a*) Clonidine and its formulations (*b*) Tablets of clonidine and chlorthalidone	Equivalent to 30 kilograms of clonidine hydrochloride	
			Bulk drugs Sulfinpyrazone	500 kg per annum	New Article
			Formulations Sulfinpyrazone 100 mg tablets Sulfinpyrazone 200 mg capsule	1 million tablets 0.7 million capsules	
			Carbamezapine	1200 kg (existing) 5000 kg (after expansion)	Substantial expansion CIL: 286 (79) dated: 26.12.79
13.	Suneeta Laboratories Ltd., 89B/90, Industrial Estate, Indore, M. P.	Indore	Amodiaquine hydrochloride IP/BP/USP	6 tonnes (existing) 30 tonnes (after expn.)	Substantial Expansion CIL: 266 (79) dated: 5.12.79
14.	Themis Chemicals Ltd., Plot No. 69, GIDC Industrial Estate, Vapi, Distt Valsad, Gujarat.	Vapi Distt. Valsad (Gujarat)	Suproxil capsule 250 mg (each capsule containing 250 mg amoxycillin anhydrous as amoxycillin trihydrate)	3 million nos	New Article LI: 502 (79) dated: 31.12.79
			Suproxil capsules 500 mg (each capsule containing 500 mg amoxycillin anhydrous as amoxycillin trihydrate)	3 million nos	
			Suproxil syrup (each 5 ml containing amoxycillin anhydrous 125 mg as amoxycillin trihydrate)	2 lakh bottles	

NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
1.	*Analgesic*			
	Buprenorphine	Temgesic	Reckitt & Colman	Switzerland
	Butorphanol	Stadol	Mead Johnson	UK
2.	*Analgesic/Tranquilliser*			
	Aspirin + Chlormezanone	Trancoprin	Sterling	UK
3.	*Antiarrhythmic*			
	Procainamide	Procain SR	Parke Davis	USA
4.	*Antibacterial*			
	Cefoxitin	Cenomycin	Daiichi Seiyaku	Japan
	Cinoxacin	Cinobac	Lilly	Brazil
	Erythromycin ethyl succinate + Acetyl sulpafurazole	Pediazole	Rose	USA
	Piperacillin	Pentcillin	Toyama	Japan
	Sisomicin	Baymicine	Bayer	France
		Sisolline	Unilabo-Centrane	France
	Ticarcillin	Ticarpenin	Beecham	Japan
5.	*Antidiarrhoeal*			
	Framycetin + Kaolin + Pectin	Sofrakay	Hoechst	Indonesia
6.	*Antiemetic*			
	Metopimazine	Vogalene	Rorer	Canada
7.	*Antihistamine*			
	Terfenadine	Teldane	Merrell	France
8.	*Antihyperlipidaemic*			
	Benzafibrate	Cedur	Boehringer Mannheim	Switzerland

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
9.	*Anti-inflammatory*			
	Fentiazac	Donorest	Wyeth	Indonesia
10.	*Antineoplastic*			
	Daunorubicin	Cerubidine	Ives	USA
11.	*Antispasmodic*			
	Diponium bromide+ magnopyrol	Spaslar	Siegfried	Indonesia
12.	*Antiviral*			
	Isoprinoside	Inosiplix	Delalande	Italy
13.	*Bronchodilator*			
	Bitolterol mesylate	Effectin	Shionogi	Japan
	Fenspiride	Pneumorel	Servier	Indonesia
14.	*Cardiac glycoside*			
	β-Methyldigoxin	Lanitop	Boehringer Mannheim	Indonesia
15.	*Cerebral vasodilator*			
	Almitrine+Ruabasine	Duxil	Servier	France
16.	*Gallstone dissolving agent*			
	Chenodeoxycholic acid	Chenofalk	Darya	Indonesia
	Ursodeoxycholic acid	De-Urcil	Giuliani	Switzerland
17.	*General anaesthetic*			
	Isoflurane	Forane	Ohio Medical	USA
18.	*Glucocorticoid*			
	Cloprednol	Cloprednol	Syntex	Belgium
19.	*Hypoglycaemic*			
	Gliquidone	Glurenorm	Boehringer Ingelheim	Indonesia
20.	*Oestrogen*			
	Oestriol succinate	Synapause	Organon	Indonesia
21.	*Prolactin inhibitor*			
	Bromocriptine	Parlodel	Sandoz	Spain

Contd.

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
22.	*Topical anti-inflammatory*			
	Bendazac	Zildasac	Chugai	Japan
23.	*Topical corticosteroid*			
	Betamethasone dipropionate	Rinderon-DH	Shionogi	Japan
	Clobetasol propionate	Dermovate	Glaxo	Canada
24.	*Tranquilleser*			
	Prazepam	Verstran	Parke Davis	Canada

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MEETINGS & SEMINARS

US to host drug regulators' conference

The US Food and Drug Administration is hosting a four day international Conference from October 28th to 31st, 1980, for top officials of all WHO-member drug registering authorities at Annapolis Naval Academy in Maryland. The meeting, jointly sponsored by FDA and WHO, will be held "*in Camera*" for fostering free discussion.

The meeting expected to be attended by about 60 people has two main topics on agenda: how to improve communications among top drug registering officials of the WHO countries and secondly the identification of appropriate areas for hcrmonisation of drug regulatory requirements.

Scrip., No. **471,** 10 (15 March 80)

UNIDO pharmaceutical meet in Mexico

Twenty six governments will participate in the UNIDO sponsored Global preparatory meeting, on the Pharmaceutical Industry, to be held in Mexico. India is one of the representatives of the Asian less developed countries. International pharmaceutical industry will be officially represented by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The UNIDO has proposed the following agenda for the meeting:

(*i*) basic principles of a model licencing arrangement for the manufacture of active substances and for drug formulations;

(*ii*) price and availability of bulk drugs and intermediates,

(*iii*) availability of technology for the manufacture of the active substances of 25 essential drugs.

The Global preparatory meeting will be followed by a Consultation Meeting which UNIDO has tentatively scheduled for Dec. 8-12,1980, possibly to be held in Vienna or Copenhagen.

Scrip, No. **475,** 11 (29 March 80).

IFPMA tenth assembly would be held in Madrid

International Federation of Pharmaceutical Manufacturers Association (IFPMA) will hold its tenth assembly on October 16th and 17th, 1980, at Madrid in Spain. The main theme of the meeting has been chosen to be "The Pharmaceutical Industry's Contribution—Present and Potential—to World Health".

Further details can be had from:

IFPMA Secretariat,
P. O. Box 328, CH-8035, Zurich,
Switzerland.

Scrip, No. **475,** 12 (29 March 80)

Seminar on Drugs (Prices Control) Order '79 and Drug Industry

A two day seminar on "Drugs (Prices Control) Order '79 and Drug Industry" was held in Bombay on 23rd and 24th February, 1980. The seminar, jointly organised by the Institute of Cost and Works Accountants of India, Western India Regional Council, Bombay and the Indian Drug Manufacturers' Association was inaugurated by Mr. S. Krishnaswamy, President, ACC. Mr. K. M. Shah, President Indian Drug Manufacturers' Association (IDMA), delivered a keynote address on the "Future Gowth of Drug Industry in India". Another keynote address delivered by Mr. Amar Singh, Managing Director, John Wyeth Laboratories was on "Impact of DPCO on the Drug Industry".

The Seminar was divided into seven sessions, including the concluding session.

The summary of the Conclusions and recommendations is as follows:

I. PRICE CONTROL:

(*a*) Selective rather than total control envisaged by D.P.C.O. would be more effective and administratively simpler.

(*b*) Price control cannot be seen in isolation and all aspects of industry *viz.* production, R & D, capital outlay, growth and long term needs and availability of drugs to consumer should be considered within the framework of the new drug policy.

(*c*) Attention should be given to the growth of all sectors of the drug industry as laid down in new Drug Policy and as envisaged by the Working Group of the Planning Commission.

(*d*) D.P.C.O. seeks to fix selling prices of drugs based on costs of inputs but does not provide for any machinery to ensure that the various inputs are in fact available at these costs to the manufacturers.

II. D.P.C.O. BULK DRUGS:

(*a*) Return allowable on bulk drug manufacture should not be based on the concept of "Reasonable Return" but should be specified at 12 and 14% post-tax on net worth in the D.P.C.O. itself taking into account the Replacement Cost of Assets. For small and medium sized units whose own capital is relatively small and whose reliance on borrowings is relatively greater; and for new units whose reserves are meagre (as compared with the old-established units); and loss-making units, a judicious blend of the following three factors, namely, net worth, total capital employed and turnover should be adopted for computing the base on which the return should be allowed.

(*b*) Provisions relating to D.P.E.A. should be deleted from D.P.C.O. both from legal and practical angle.

III. D.P.C.O. AND FORMULATION:

(*a*) With 40 to 55% mark-ups for essential products it is not possible to make profit and hence there will be a tendency to divert to category III products, thereby creating shortages of category I and II formulations.

(*b*) Whether the mark-ups are adequate or not, it is noticed that the way the price control is exercised or implemented, even these mark-ups are only paper mark-ups and do not exist in reality.

(*c*) There should be a machinery and a provision in the D.P.C.O. for granting speedy automatic increase in prices of drugs and formulations within certain timelimits. Beyond this time limit, manufacturers should be allowed to increase the price as per his application which is certified by Cost/Chartered Accountant.

(*d*) Time-limits should be laid down in the various provisions of the D.P.C.O. itself within which the Government should give decisions.

(*e*) There is no logical basis for excluding certain expenses from costs and including them as part of return on investment/pre - tax return.

IV. D.P.C.O. IMPLEMENTATIONS:

(*a*) Bureau of Industrial Costs and Prices studies should be shared with the industry. Details of actual costs and mark-ups taken by BICP while fixing the prices must be given to the companies.

(*b*) Machinery/forms should be simplified (in consultation with ICWAI) to avoid the delays.

(*c*) Institute of Cost & Works Accountants of India should be associated with the effort to evolve acceptable formula for quicker and more automatic price increases.

V. FUTURE OF DRUG INDUSTRY:

(*a*) Drug Industry with the assistance of a professional body like the Cost Institute should improve its credibility with the legislators and the Government who influence the future of the industry and ensure that the industry is depoliticalised.

(*b*) R & D should be encouraged by removing direct or indirect constraints put on the drug industry.

(*c*) Overall control on the industry should be such as to leave adequate resources for growth.

VI. GENERAL:

Organisers should develop a statement of recommendations based on the record of proceedings taped/being taken down and submit to the Government authorities concerned.

BOOK REVIEWS

The International Pharmacopoeia, Third Edition, Volume 1: General methods of analysis.

World Health Organization, Geneva, 1979, Pages 223, Price: Sw. fr. 24.

The *International Pharmacopoeia* is published by the World Health Organization with a view to improving the quality control of all drugs and pharmaceutical substances. Published by virtue of a resolution of the Third World Health Assembly, the first edition appeared in 1951 and the second in 1955, followed by a supplement in 1959. The present (third) edition contains the results of a periodic revision of international standards, requirements, and guidelines for prophylactic and therapeutic substances.

It is planned to publish the *International Pharmacopoeia* in five volumes between 1979 and 1983. The present volume, which is the first one, contains the description of 42 general methods of analysis, and subsequent volumes will contain quality specifications for individual drugs, particularly those that are most widely used in health care.

The methods and procedures described were selected in collaboration with members of the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations and many other specialists from different countries. Methods retained from the previous editions were inproved by making use of newly developed analytical tools. Various technical and economic constraints were fully considered in recommending procedures for analyses, which, it is hoped will permit improved quality control in both developed and developing countries.

While the recommended methods and specifications would not have a legal status as such in any country, unless expressly introduced into the national legislature, they are intended to serve as references for the national authorities.

All units of measurement expressed in this edition are based on the International System of Units (SI). ▭

Environmental Health Criteria 14: Ultraviolet radiation.

Published under the joint sponsorship of the United Nations Environment Programme, the World Health Organization and the International Radiation Protection Association, World Health Organization, Geneva, 1979, Pages 110, Price: Sw. fr. 10.-.

The volume is based on evaluation of original publications and reviews. The subjects covered include the properties and measurements of UVR, its biological effects, and beneficial and harmful health effects on man. The book provides an evaluation of the health risks to man and finally describes the range of exposure limits to UVR, existing protection and control measures such as containment of UVR sources, and methods for personal protection.

The report was prepared by experts from various countries and international organizations, and takes into consideration comments received from national institutions collaborating with the WHO Environmental Health Criteria Programme and from the International Labour Organization, the World Meteorological Organisation, and the International Atomic Energy Agency.

The publication will be of interest to departments of health, housing and town planning, occupational health and the environment, to dermatologists and oncologists, to national regulatory agencies, and to public health workers. □

Human viruses in water, wastewater and soil.

Report of a WHO Scientific Group. *World Health Organization Technical Report Series*, No. 639, 1979, Pages 50. Price: Sw. fr. 4

Research has shown that enteric viruses can easily survive present sewage treatment methods and may persist for several months in natural waters. And it may reasonably be assumed that where sanitation is less advanced enteric viruses exist in great abundance in water sources. The present report makes an assessment of the public health importance of enteric viruses of human origin in water, wastewater and soil, and of the nature of the risks for exposed persons. It defines the limits of epidemiological investigations, and discusses the various sources of infection—wastewater, drinking water, seawater, water used for recreation or applied to soil and crops, groundwater, and aerosols. Also dealt with are virus monitoring in different situations, various treatment processes used for the removal of viruses from wastewater, sludge, and drinking water, respectively, as well as to the decontamination measures applied to ensure the safety of recycled water. With reference to the reuse of wastewater for potable supplies, guidelines are set forth regarding the permissible limits of viral contamination. The report ends with a series of recommendations outlining priority areas for further research.

In view of the growing importance of the problems described, which are being compounded by increasing demands on available water resources as a result of population growth and concomitant industrial expansion, this publication is of direct concern not only to virologists and water-quality controllers, but also to all persons interested in water and soil pollution and to those responsible for public health and economic planning.

□

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Focus

Penicillins

Dr. P. K. Ghosh*

A large number of natural penicillins are known of which only penicillins G and V are produced in the country. While some quantities of these are directly used for making formulations, the rest are mainly converted into injectable sodium and procaine salts. A part of penicillin G is also used for making injectable benzathine penicillin. Recently, one company has started making 6-aminopenicillianic acid (6-APA) from penicillin G.

Demand:

The Working Group on Drugs & Pharmaceuticals of the Planning Commission had estimated the demand for penicillins at 415 mmu in 1979-80, going upto 700 mmu by 1982-83 and 875 mmu by 1983-84. These figures include the requirements for direct formulations as potassium, sodium, procaine and benzathine penicillins as well as for conversion into 6-APA. During 1980-81 about 100 mmu are expected to be used for making 6-APA and the requirements of penicillins may, therefore, be of the order of 430 mmu. In 1981-82 the demand may go upto 550 mmu.

Supply:

The following is the break-up of the approved capacity as on date for the basic production of penicillins :

Company	Approved capacity (mmu)		
	Industrial Licence	Letter of intent	Total
Indian Drugs & Pharmaceuticals Ltd., Rishikesh	230	—	230
Hindustan Antibiotics Ltd. Pimpri	84	76	160
Alembic Chemical Works Co. Ltd., Baroda	100	—	100
Standard Pharmaceuticals Ltd., Serampore	40	45	85
		G. Total	575

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The total production of penicillins in 1977-78 was about 312 mmu which increased only marginally to 320 mmu in 1978-79. During April to December 1979, it was 241 mmu and the production is likely to remain at 320 mmu during the year 1979-80. In 1979-80 there was negligible conversion of penicillins to 6-APA. However, during the next year if the 6 APA plant already commissioned achieves normal production, it would consume about 100 mmu of penicillin G and in that case there is likely to be some shortage of the latter, if indigenous production does not keep pace with demand. However, there is every likelihood of the production increasing as two units are in the process of completion of their expansion programmes and another unit is likely to raise its current level of production by using a high potency strain.

Growth rate:

Past	(1970-80):	Average about 4.45% per year
Future	(1980-84):	Expected to be 20-22% per year, mainly on account of semi-synthetic penicillins.

Price:

The current approved prices for various penicillins are:

Item	*Rs. per B.U.*
Potassium penicillin G IP	644
Sodium penicillin G	639
Procaine penicillin G	595
Potassium penicillin V	942
Potassium penicillin Ist crystals	431

Outlook:

As per the New Drug Policy (1979) the basic production of penicillins is reserved for the public sector. Basic production is capital intensive and its economics depends very much on the technological inputs. While ten years ago producers were satisfied with a broth potency of 6000 to 10,000 units/ml in a seeding to harvesting time of about 180 hours, today an average potency of less than 20,000 units/ml in 200 hours is not considered economical. Plants in operation elsewhere have an average potency of more than 30,000 units/ml and sometimes as high as 50,000 to 60,000 units/ml. The recovery efficiency has also been increased considerably from about 45 to 65% from unfiltered broth to potassium penicillin. Today an yield of 60 B. U. per M^3 of fermented broth per month in terms of potassium penicillin is considered satisfactory.

The demand for penicillins in the form of formulations such as potassium, sodium, procaine and benzathine salts/complexes is expected to grow at the rate of 4 to 4.5% per annum. The demand for semi-synthetic betalactam antibiotics such as ampicillin, amoxycillin, epicillin, cloxacillin, dicloxacillin etc. is also likely to increase substantially from the present level of about 100 MT (1978-79) to 220-250 MT by 1983 84, which would result in raising the consumption of penicillin to 475 mmu by 1983-84. Some medium and long-acting penicillins like procaine-penicillins and benzathine-penicillins are likely to enter the market in hitherto unexplored rural areas. At the same time the market in urban areas may not grow due to the widespread development of penicillin-resistant micro-organisms as well as the risk of occurrence of systemic reactions and on account of the availability of the safer erythromycin, broad-spectrum tetracyclines, chloramphenicol and long-acting sulphas. At best, hospital consumption might show a marginal increase.

If the manufacturers of betalactam antibiotics base their production on 6-APA made from indigenously produced potassium penicillins G and V only, it would lead to establishment of new capacities. The potential for conversion of potassium penicillins into semi-synthetic betalactam antibiotics is so high that the present annual growth rate of 4-4.5% for penicillins may well go upto 20-22%.

□

DRUG INDUSTRY

General News

Essential drugs' supply to be maintained

Department of Chemicals and Fertilisers which monitors the production of life-saving bulk drugs and formulations has received reports from various states which show that chloramphenicol, erythromycin, procaine hydrochloride, dapsone, chloroquin phosphate and PAS and its salts are in short supply. There has been a marginal fall in the production of essential and life-saving drugs in 1979-80, as compared to last year due to various reasons. Efforts are being made to arrange the imports of these drugs and for that actual users have been permitted by the Government. This is in addition to the imports being done by CPC.

Air lifting of imports, wherever necessary, has also been authorised. Import duty on aluminium foil—a packaging material—has also been reduced. Its import has been liberalised under Open General Licence system. Bottle packing without any change in price hike has also been permitted.

Generic name to get prominence in drug lebelling

The Union Ministry of Health and Family Welfare has proposed a draft amendment of clause (I) of sub-rule (I) of the rule 96 of the Drugs and Cosmetics Rules 1945. Under revised rule labelling of drugs will have to be changed in such a way that the generic name is printed more prominently than the brand name. The brand name will follow immediately after or under the generic name.

Drug industry sources have expressed their surprise over this reported move pointing out that instead of resorting to de-emphasise brand name, government should evaluate its previous move wherein no brand name was to be allowed for single ingredient new drug introduced for the first time in the country. They point out that the amendment would violate Trade and Merchandise Marks Act which allows the owner of a brand name to display it as conspicuously as possible.

Sources further feel that this move could be an alternative by the Ministry to the complete abolition of brand names. Moreover, this would also involve a considerable expenditure for firms as complete redesigning and reprinting of packaging material will have to be done.

Primary health care: ICMR to aid development

A conference to evaluate Primary Health Programmes, organised by Indian Council of Medical Research in collaboration with World Health Organisation, has entrusted ICMR with the development of guidelines and methodologies for primary health care.

The rural population has welcomed the scheme of community health workers and according to Dr. R. S. Arole, the communication between the health care worker and the recipient community members was the most essential part of any primary health programme. The first step, he stated, is to meet the basic needs of employment, food and water through rural development projects.

It is necessary to dispel fears that the scheme may fail on account of the non-availability of drugs, medical kits, and financial problems like the delay in the payment of salaries etc..

Private sector invested Rs. 48 crores during April 78 to January 80

Mr. Veerendra Patil, the Union minister for Petroleum, Chemicals & Fertilisers told Rajya Sabha that during April 78-January 80 the private sector was granted industrial approvals to invest Rs. 48 crores, compared to Rs. 51 crores by public sector and Rs. 10 crores by Indian companies under the licensing exemption scheme. If the trends continued like this the sixth plan target of the production of Rs. 1900 crore worth of formulations and Rs. 475 crore worth of bulk drugs as envisaged by the working group of the ministry will be achieved.

MRTP stops Glaxo inquiry

The Monopolies and Restrictive Trade Practices Commission, which was inquiring into the allegations that Glaxo Laboratories use its entire betamethasone alcohol for itself, instead of distributing to other firms for formulations has decided not to proceed with the inquiry.

The method of distribution, as suggested by the company, was accepted by the Commission which agreed that company was entitled to use its entire production for its own captive use. The company's contention that it would continue to offer for sale surplus quantity of betamethasone alcohol, if any, to actual bonafide formulators has also been accepted by the Commission.

Chloramphenicol shortage: anti-typhoid drugs production hit

Shortage of chloramphenicol, an important bulk drug for the manufacture of anti-typhoid drugs, has led to a fall in the manufacture of these formulations. Neither indigenous nor imported chloramphenicol is available in adequate quantity at present. The two units engaged in the production of this bulk drug have a total production capacity of 56 tonnes which is far short of the demand of 130-150 tonnes per annum. This deficit is met through imports, canalised through CPC.

Of the two units producing chloramphenicol, one is operating at lesser capacity because it is of the view that present selling price of Rs. 586/kg is unremunerative in view of the growing input costs. This unit has given up its expansion programme also.

The second unit which was given a licence after a considerable delay, to double its capacity is now having second thoughts about its expansion programme, again because of escalating costs and static prices.

Meanwhile, other countries are also experiencing this chloramphenicol shortage and adequate supplies are not available even to CPC. Industry wants that issue of revision of price for chloramphenicol should be taken up separately and urgently.

National strategy on cancer control

The Indian Council of Medical Research is preparing plans for a national strategy on cancer control with a special emphasis on research in cancer detection and present treatment procedures. This is consequential to WHO's call to accord top priority to develop and strengthen cancer control measures in SE-Asia.

According to rough estimates-since no—systematic survey has been done so far—five lakh people die of cancer every year in India. And this figure may still increase due to various environmental factors. Of these deaths atleast half can be attributed to cancer of uterine cervix among women and cancers of throat and mouth among men, which are quite different from the types of cancer prevalent in Europe and other developing countries.

Now 20 centres have been selected for administering 'Pap Smear Test' to detect precancerous lesions of uterine cervix among women at the time of delivery. The council has also highlighted the need to strengthen the present cancer registeries and for opening up of at least three more to cover different regions so that incidence of this disease could be effectively monitored.

OPPI Annual general meeting—call for doubling of drug output

Addressing the annual general meeting of the Organisation of Pharmaceutical Producers of India, Mr. H. N. Dutt Gupta, President, said the country's demand for drugs could be met only if all the sectors of the industry were allowed to utilise their full production capacities. The curbs and restrictions imposed on the organised sector of the industry under the new drug policy are contrary to the objective of achieving higher production target. The production of medicines and drugs will have to be doubled in the next three years to meet the projected demand of the industry.

According to him, the drug prices in our country are not high; in fact, prices in many developed countries were much higher. Several units have become sick because the production cost has increased considerably during the last few years, whereas the prices of both bulk drugs and finished medicines have remained frozen. This has led to serious consequences.

Mr. Dutt Gupta said that 25-30 per cent of the prices the consumer pays goes for taxes and duties alone and this is among the highest levies imposed by any country in the world. Also the Indian pharmaceutical market is so tightly regulated and legislated upon that atleast seven ministries and departments of the Union Government control and regulate the industry. State level controls and regulations are the additional ones. This 'plethora of controls' results in inevitable delays in decision making at every point of control which subsequently leads to slow down in investment, growth with consequent loss of production, employment and revenue to the state. Mr. Dutt Gupta called for a rational and long-term drug pricing policy which should be reasonable for both the consumers and the producers and should help the industry grow.

Algerian drug policy outlined

The Algerian Health Minister Mr. Abderrazak Bouhara detailed the first comprehensive definition of his government's drug policy while addressing the new Nomenclature Committee. According to him the government will implement a wise policy of drug procurement, warehousing, distribution and use. The annual per capita drug consumption is about AD 45 compared to AD 225 in Hungary and AD 265 in US. The government drug costs have increased in less than 10 years from AD 145 million to AD 800 million but this increase is proportional to that of total health care expenses. The government will not take such steps so as to have a restrictive drug policy. The government will try to import only those drugs which qualify the therapeutic needs of the country. It will also reduce its excessive dependence on any one supplier of drugs. The new nomenclature will keep the doctors better informed.

The local production of drugs which is only 12% of the total consumption will be given a boost by setting up four units in addition to the three existing drug manufacturing units. Though total import substitution is not possible, according to Mr. Bouhara, drugs to be manufactured locally will be selected on the basis of careful assessment of needs by Nomenclature committee.

Scrip, No. **480,** 12 (16 April 80)

Clinical investigator's shortage likely in USA

Dr. Edward H. Kass, Medical Professor at Harvard and Dr. John J. Burns, Research Vice-President of Hoffmann La Roche have cautioned the drug industry of an impending shortage of young clinical investigators in USA. These young persons now working in universities or at research oriented hospitals are reluctant to become involved in studies of anything less than a potential "blockbuster" drug. The present merit promotion system is responsible for this state of affairs as this tends to ignore those who are not involved in high calibre research. This shortage has resulted in less rigorous testing and poorer trial of new drugs, and needs immediate attention.

Scrip, No. **476 477,** 10(5 April 80)

Japan may grant patent to recombinant DNA products

The Japanese government's Patent Agency has decided that all domestic and foreign patent applications involving genetic engineering other than simple well-known recombinant DNA techniques and general applications, will be patentable in Japan. But the applications will have to fulfil, the national safety guidelines on genetic engineering issued by the Japanese Council for Science and Technology.

Scrip, No. **481,** 13 (19 April 80)

Japanese firms to pay compensation to SMON victims

In an out of the court settlement the three Japanese drug firms namely Seiyaku Co., Takeda Chemical Industry Ltd., and Ciba-Geigy Japan Ltd., have agreed to pay compensation to the victims of their drug quinoform. This is the fourth settlement of its kind. The drug caused Subacute-Myelo-Optico-Neuropathy in its 47 users who will get a compensation of around 5 million dollars; each victim will get a lumpsum of 55,000 to 190,000 dollars. In addition to this, companies have also agreed to pay 245 to 410 dollars per month to 8 persons in the advanced stage of the disease. Dependents of six persons who lost their lives will get 4,000 dollars as condolence money.

National drug-policy and National health policy to be interlinked

Addressing the annual general meeting of the Organisation of Pharmaceutical Producers of India in Bombay, Dr. V. Ramalingaswami, Director-General of ICMR stated that the Union Ministry of Health is in the process of evolving a national health policy which, according to him, would be required to be closely linked to national drug policy. A draft paper on the national health policy has already been prepared for discussion.

Dr. Ramalingaswami referred to WHO call of "Health for all by 2000 AD" and outlined the following six-point programme as a guide for achieving this objective: (1) Each country should draw up a basic drugs list, taking into account its pattern of disease and health infrastructure; (2) Drugs should be purchased in bulk to reduce costs; (3) Indigenous production capacity and pharmaceutical self-sufficiency should be promoted; (4) Traditional remedies in their composite forms should be used for curing diseases where modern medicine fails; (5) Self-sufficiency should also be promoted on a regional basis between the developing countries and (6) A rational pricing policy should be developed with the emphasis on price regulation rather than price fixing.

Company Reports

CPC achieves a record turn-over

The State Chemicals and Pharmaceuticals Corporation (CPC), a subsidiary of State Trading Corporation, has increased its turn-over from Rs. 107 crores for the year 1978-79 to Rs. 131 crore for 1979-80. This record turn-over is 22 per cent increase over the previous year. Of Rs 131 crores, Rs. 124 crore is the import figure compared to Rs. 100 crore in 1978-79.

The export figure of Rs. 7 crore was same as that for last year. Profits amounted to Rs. 5.3 crore pre-tax, and this was higher by 39 percent compared to 1978-79. CPC sold Rs. 92 crore worth of 43 canalised items compared to Rs. 69 crore for 78-79, a rise of 33 per cent.

Isabgul unit to be set up in Gujarat

Gujarat Drugs and Chemicals Ltd., a new company being jointly promoted by Gujarat Industrial Corporation Ltd., and Indian Drugs and Pharmaceuticals Ltd., will set up a Rs. 1.5 crore psyllium husk (isabgul) processing project. IDPL has supplied the indigenously developed technology based on the research carried out at Central Drug Research Institute, Lucknow. So far a few foreign countries were having a monopoly over this know-how and it was a closely guarded secret. Gujarat being the largest producer of psyllium husk used to export it for processing it in foreign countries.

Isabgul efficacy in the treatment of constipation and other bowel disorders is well established. But taken in raw form it is sticky and tasteless. By this process it will be coated so as to make it palatable and easy to swallow.

The proposed project will produce 400 tonnes of palatable psyllium husk and 145 million tablets of different preparations per annum. It will be located at Mehsana, an industrially backward district. Working at full capacity the sales turnover would be around Rs. 3.25 crore per annum and will have an employment potential of about 170 persons.

Pethidine production to be raised

Gluconate Ltd., the only manufacturer of pethidine in India has been granted licence ro produce 2,000 kg of this drug, 1600 kg more than the present capacity of 400 kg.

The company is now making about 60 products and has plans to raise its turnover to Rs. 4 crore by 1983. The product range is also being revised. The production of capsules and antibiotic tablets would be doubled and syrup production reduced.

Private firm to construct and run hospitals in India

Apollo Hospitals Enterprise Ltd., a private company, has been allowed by the government to construct and run a network of hospitals in different cities of India. This sort of permission has been granted for the first time.

According to Dr. Pratap C. Reddy, chairman of the company, the company has an equity of Rs. 2.6 crore and will raise a loan of Rs. 5.3 crore. The work on the first of such hospitals has already started in Madras and this 250 bed hospital is expected to open in early 1982. After the completion of Madras Hospital similar complexes will be started in Trivendrum, Bangalore and Delhi. The hospitals will have multi-speciality wards. Fifteen per cent of the beds and forty per cent of the out-patient treatment capacity will be available free of cost to deserving patients. These hospitals will have attached research facilities.

Bengal-Chemicals and Pharmaceuticals to be nationalized

The Union Minister for Petroleum, Mr. Veerandra Patil, told Rajya Sabha that Bengal Chemical and Pharmaceuticals may be nationalized very soon. Management of the company is already with the government.

Kerala drug unit claims record sale

S. S. Pillai, the Managing Director of Kerala State Drugs & Pharmaceuticals Ltd., has claimed an all time high sales turnover of Rs. 3.05 crore during the financial year 1979-80. According to him, the company's Vitamin A plant will be put into operation in 1981.

May & Baker profit goes down

May & Baker, which earned a gross profit of Rs. 1.53 crore in 1978, slid to a profit of Rs. 1.30 crores for 1979; the sales however improved from Rs. 16 74 crores in 1978 to Rs. 16.96 crore in 1979. This slump in profit is attributed to industrial unrest during 1979 which resulted in a production loss of about Rs. 1 crore.

After providing Rs. 29.36 lakh for depreciation, Rs. 9.58 lakh for investment allowance reserve and Rs. 46 83 lakh for taxation a sum of Rs. 6 lakh was transferred to the general reserves.

Drug production touches Rs. 1250 crore in 1978-79

Drug production in India during the year ending March, 79 was Rs. 1250 crore a 17.5% increase over Rs. 1064 crore reported for 1977-78, according to Organisation of Pharmaceutical Producers of India. The break up of production is as follows:

	1978-79 Rs. crore	% change	1977-78 Rs. crore
Bulk drugs	200	22.0	150
Formulations	1,050	16.7	700
Total	1,250	17.5	850

Foreign sector led the formulation production field by contributing 44% of the total, whereas the organised and private sector led in bulk drug production (37.5% of the total). The public sector accounted for 6.0% of formulations and 24.5% of bulk drugs production. The figures are as given below:—

	Formulations		Bulk drugs	
	Rs. crore	% total	Rs. crore	% total
Foreign sector	460	44.0	56	28.0
Private sector (organised)	340	32.0	75	37.5
Public sector	60	6.0	49	24.5
Small scale sector	190	18.0	20	10.0
Total	1050	100	200	100

Among bulk drugs the production figures by therapeutic categorywise was as follows:

	Value in crores	% total	Foreign cos. share
Antibiotics	61.0	30.5	21.0
Analgesics/antipyretics/ antirheumatics	24.0	12.0	13.0
Vitamins	21.0	10.5	25.0
Sulphonamides	18.0	9.0	31.0
Antituberculosis	9.0	4.5	14.0
Corticosteroids & sex hormones	9.6	4.8	91.0
Antiamoebics	6.0	3.0	16.0
Antimalarials	4.0	2.0	48.0
Antidiabetics	3.0	1.5	93.0
Others	44.4	22.2	29.0
Total	200	100	27.9

Glaxo tops the drug firms list

According to a survey by the *Econoimic Time Research Bureau*, the list of top 250 public limited companies includes ten pharmaceutical firms also. Among these Glaxo occupies the top place, followed by Ciba-Geigy. The list is as follows:

Company	Net worth Rs. in crore	Net sales Rs. in cr.ore	Profit after tax Rs. in crore
Glaxo Labs	25.88	58.44	3.27
Ciba-Geigy	18.27	52.66	3.68
Pfizer	15.83	36.61	2.63
Bayer India	13.89	42.19	2.7
Suhrid-Geigy	11.72	32.27	1.62
Alkali & Chemical Corporation	10.78	45.81	6.8
Cynamid India	9.29	18·2	1.7
Hoechst Pharma	8.84	32.29	1.23
Sandoz India	8.25	39.98	1.58
Alembic Chemical Works	6.99	30.9	0.73

Basic chemicals' export short of target

The Basic Chemicals, Pharmaceuticals and Cosmetics Export Promotion Council, which had set an export target of Rs. 200 crores for the current year could export only Rs. 150.22 crores worth of items this year. This is 14 per cent less compared to the Rs. 174.84 crore figure of last year.

Export of some items such as surgical dressings and other medicaments registered a fall from Rs. 2 crore and Rs. 16.47 crore to Rs. 84 lakhs and Rs. 11.62 crore respectively. The fall in export of medical dressings is mainly due to the reduction in cash compensatory support from 20 to 7.5 per cent. In case of other medicaments, the shortoge of some essential bulk drugs, delay in the fixation and settlement of claims and shipment difficulties were some of the constraints.

According to the council spokesman a target of Rs. 250 crore during 1980-81 could easily be achieved if various constraints are removed and raw material is made available freely and at reasonable prices.

Rewa Drugs and Chemicals to enter market

Rewa Drugs and Chemicals, a joint sector firm will issue in July next for public subscription 1.8 lakh equity shares of Rs. 10 each payable at par.

The company is setting up a plant at Roha in Maharashtra for the manufacture of a drug intermediate, 8-hydroxyquinoline. The project is estimated to cost Rs. 81 lakhs and the production may start by this year end. The drug intermediate an import substitute will be used to manufacture mexaform, entrovioform and other iodochlor derivatives.

Searle dividend at 20 per cent

Searle (India) has maintained the rate of dividend at 20 per cent for 1979 on expanded capital. This comes out to be 28 per cent on old capital. This higher distribution is because of a rise in the company's sales and profits. Its gross profit is up by 46 per cent from 65.25 lakhs in 1978 to Rs. 95.12 lakhs for 1979. Sales have increased from Rs. 4.02 crore in 1978 to Rs. 5.22 crore in 1979, an increase of 30 per cent.

British industry pharmaceutical export growth static

In the first nine months of 1979 the pharmaceutical export by British Drug Industry was valued at £ 470.4 million; it is down by 3.8 per cent compared to same period last year.

It is hoped that full year figures will be almost similar to those of 1978. This export fall is consequential to fall in export to Iran and Nigeria. Imports (£ 167.1 million) were up by 14.6 per cent during this period.

ABPI News, No. **178,** 1 (Dec 79)

French drug production up by 9% in 1979

Fr. 20,479.7 million worth of pharmaceuticals for human use were produced during 1979 in France. This is up by 9.4% over 1978 figure of Fr. 18,723.3 million. Exports of pharmaceutical specialities jumped by 20.8% from Fr. 3131.5 million in 1978 to Fr. 3,781.8

million in 1979. Imports during this year were only Fr. 384.5 million.

Scrip, No. **478/479,** 4 (12 April 80)

Spain's pharmaceutical specialities export touches $ 61.5 million

Spain's foreign trade balance in 1978 for pharmaceutical specialities was positive for the first time in four years. Exports amounted to $ 61.5 million compared to imports of $ 58.2 million. Exports increased by 33.8% in comparison to import increase of 9.9%. Exports were mainly to West Europe (52%) and Latin America (21%) followed by Belgium (6.7%), Panama (6%), Portugal (5.75%) and Poland (4.9%). Imports were from USA (22.8%), West Germany (14%), Switzerland (12.8%), UK (10.5%) and Denmark (10.4%).

Scrip, No. **483**, 3 (26 April 80)

UK trade balance drops in 1979

According to the UK Department of Trade, the exports of medicinal and pharmaceutical products in 1979 amounted to £ 639 million compared with £ 654 million in 1978, a drop of 2.3%. Imports in 1979 were £ 23.3 million compared with £ 20 million in 1978, an increase of 15.9%. The 1979 balance of trade was £ 406 million compared with £ 453 million in 1978, a drop of 10.4%.

Scrip, No. **478/479,** 2 (12 April 80)

World pharmaceuticals' sales touch $ 64 billion

According to World Drug Market Manual 1980-81, the global pharmaceutical sales for 1979 are estimated at $ 64.57 billion.

Following is the list of ten leading drug markets:

United States ($ 11,360 million, 17.6% of World share), Japan (8,790 million, 13.6) ; West Germany (5,000 million, 7.7); France (4,330 million, 6.7); Italy (2,380 million, 3.7); Britain (2,000 million, 3.1); Brazil (1,890 million, 2.9), Spain (1,570 million, 2.4); Argentina (1,400 million, 2.2) and Mexico (907 million, 1.4).

ABPI News, No. **178, 2** (Dec. 79)

Research and Development

Garlic is good for meningitis

Garlic's efficacy in curing hypertension, hardening of arteries, cancerous tumours, excessive blood sugar as in diabetes, and intestinal infections is well known. It has now been found to be more effective compared to allopathic drugs in the treatment of meningitis. A study published in a Chinese medical journal reports that 16 cases of meningitis treated with garlic were cured and in five cases all symptoms of the brain disease vanished. Five other cases ended fatally.

The allopathic drug, amphotericin used for curing this disease has been found to be effective in only 15 per cent of the patients. The garlic extract is administered either orally or intramuscularly or intravenously. In USSR the garlic extract is used as an antibiotic. In folklore medicine it is given in case of senility, heart disease and menstrual disorders.

New abortifacient developed

Scientists working at the Regional Research Laboratory, Jammu, have developed a new drug 'Vascine' from *Adhatoda vasica*. The drug, apart from aiding in child birth will also be useful for medical termination of pregnancy. The activity of the drug is attributed to the presence of oxytocin, ergot and prostaglandin like substances.

HL-725: a new antihypertensive drug

Scientists working at the Hoechst Research Centre, Bombay have successfully developed a powerful anti-hypertensive drug, HL-725. After completing pre-clinical studies, the centre has sought permission from the Drug Controller of India to commence its clinical trials. This centre is mainly engaged in screening of Indian medicinal plants and nearly 800 plants have been investigated so far. The Hoechst Research Centre has also extracted another drug called Forskolin from an Indian plant which has the property of contracting the heart and lowering the blood pressure. It is at present undergoing toxicological tests. Since its inception at Mulund in Bombay, Hoechst is engaged in drug production from the basic stage and is manufacturing 16 basic bulk drugs.

Curd may help lower cholestrol level

A study conducted at the Indian Veterinary Research Institute, Izzatnagar, has reported that curd helps in lowering the cholestrol levels. Twenty rabbits were fed with 500 mg of cholestrol daily for a month and then 100 mg daily for the next two months. Of these, some were given curd supplemented diet, compared to ordinary diet of control group. Upto 30th day all rabbits were healthy but after that those in control group started showing signs of weakness, loss of body weight and anaemia. The rabbits having curds supplemented diet were having significantly less cholestrol levels on 30th, 60th and 90th day compared to the control group. Though curds reduce the cholestrol, total amount of cholestrol consumed is not neutralised fully and more studies are needed before reaching a conclusion.

India to make single cell protein for human consumption

Single Cell Protein (SCP), already in use in many Western Countries will be manufactured by the State Industrial Investment Corporation of Maharastra (SICOM) for human consumption in India. SICOM has asked for its samples from foreign countries for testing by the State Food & Drugs Administration to get the project cleared. SCP will be a packaged food either in the form of a bar or in tablet, with 50-60 per cent protein contents. The estimated cost of project is around Rs. 8 crore. Since technologies based on various raw materials including molasses are available, SICOM project would go for molasses for production because of its low price and availability and for this 35000 tonnes of molasses per annum will be required.

A new technique for treating genetic and blood disorders and cancer

A team of scientists working at University of California, Los Angeles has perfected a new treatment for sickle cell anaemia and other blood disorders. To treat sickle cell anaemia, thalassemia and other diseases, where a gene defect prevents the bonemarrow from making normal blood cells, cells from patient's own bonemarrow would be taken and two new genes inserted in them, one to correct the defect and the other for resistance to some drugs. The cells would be then put back and the patient would take small regular doses of the drug. Over a period of few months the new cells with healthy genes would gradually replace the patient's own genetically defective cells because of the competitive advantage of drug resistance.

The scientist could achieve this success of insertion of new gene into cells by inserting bonemarrow cells of mice with new genes. The new genes functioned when the cells were reintroduced into the living animal.

This technique can also help in cancer treatment where the bonemarrow is a target of anticancer drugs. Dr. Martin J. Cline of the School of Medicine has used a recombinant DNA technique developed by Dr. Richard Axel of Columbia to insert into mouse cells a gene for resistance to the anti-cancer drug methotrexate. This drug attacks the bonemarrow thus inhibiting new blood formation. A few of the mouse cells which pick up the drug resistant genes when inserted back into living mice multiply to fill 70% or more of the bonemarrow, as long as the mice were kept on small regular doses of methotrexate. This happened because the new cells could withstand the drug and had a competitive advantage over the normal bonemarrow cells which were more susceptible to the drug. Eventually this technique may help cancer patients in tolerating higher doses of drugs.

Enzyme surgery for cataract

Dr. Joseph Spina, Jr., a Philadelphia Surgeon, has sought the permission of US Food and Drug Administration for using an enzyme as an adjunct to cataract surgery on his patients. He has successfully applied the new technique to hundreds of animals and human eyes from an eye bank. Dr. Spina claims that the present microsurgery is an improvement over the older methods and would simplify the existing technique. The older technique requires nearly one inch incision but Dr. Spina's technique requires a smaller incision. It enables the surgeon to remove the lens with a cut wide enough for a needle one hundredth of an inch wide. A hollow needle is used to inject a microscopic dose of trypsin, a digestive enzyme, to liquify and digest the semi-solid interior of the lens which is made up of protein without harming other parts of the eye. When the trypsin melts the lens, it can be removed by sucking through the same hollow needle.

Estrogen in heavy dose may cause cancer

According to a study published in Journal of the American Medical Association, women with intact ovaries who take the sex hormone estrogen in heavy doses as a part of post-menopausal therapy have 2½ times more chance of getting breast cancer than the women who do not go for this therapy.

The risk appeared to be inconsistent at low estrogen dosages and was undetectable in women who had their ovaries removed. The study conducted at two homes for retired persons in Los Angeles further shows that women having a natural menopause and receiving 1.25 mg of estrogen daily for about three years have increased probability of getting breast cancer from six to twelve per cent.

Fracture cure through electricity

The US Government has accepted the claims made since long by researchers that electrical impulses stimulate bone growth and could be effective in cure of fractures. The US Food & Drug Administration has approved three such devices which could heal fractures with electric current. The treatment is an alternative to a bone graft and achieved 80-90 per cent success. Though the doctors fail to explain the reason for stimulation of bone growth by electricity, they feel that electricity initiates the chemical processes that take place in natural bone development. Since 1970, Dr. Brighton, in his clinical trials, has used electric current on 210 patients whose fractures remained unhealed on an average for 2.6 years. This new therapy healed 85 per cent of the patients in 12 weeks or less. Brighton's device consists of an electrical circuit installed under the cast, a small battery emitting steady electric signals to a cathode electrode implanted near to the fractures. For 12 weeks current is passed through the circuit 12 hours a day and the healing is perfect. The second device generates an electromagnetic field around the fractured area by an externally mounted coil to promote bone growth. In the third device produced by Teletronics Propriety Ltd., the electrode is used which is left in the body after the fracture is healed.

Transplanting heart and lungs together

Stanford University Medical Centre surgeons, Drs. Shumaray and Bruce Reitz, have claimed that after some time they may transplant the heart and lungs together. They have achieved success in heart and lung transplant in monkeys, one of which is reported alive even six months after operation. According to them, lung transplants have mostly failed because the body rejects the new lung. But this could be improved upon by transplanting the entire cardio-pulmonary system.

New method to treat heat stroke

Drs. J. S. Weiner and Mustafa Khogali of the School of Hygiene and Tropical Medicine, London have found a way to treat heat stroke victims. Heat stroke affects scores of Indians every year during peak summer and eighty per cent of the victims die when their body temperature reaches as high as 42°C. The London team has perfected a method of quick reduction of the body temperature of the victims.

The technique consists of a wire mesh bed suspended over a bath. The patient is sprayed from above and below with cold water and warm air, a combination that aids in faster evaporation and rapid cooling. This method lowers the body temperature much faster compared to traditional method of cooling the victims in an air conditioned room or giving him cold water immersion. The present method takes only 20 to 40 minutes to bring body temperature down to normal.

New sweetner for diabetics

A new sweetner called 'Talin' which is 3000 times sweeter than cane sugar is under preparation in Britain using genetic engineering techniques. Talin, an extract of the wild berries that grow in West African rain forest will be produced by certain microbes, by transferring the natural protein producing functions to these microbes. The sweetner can be used for the diabetics since it is of a plant origin and is non-toxic.

Sleep inducing substance

A team of Japanese research workers headed by Dr. Koji Uchizono, working at Japan's Governmental National Physiological Research Institute, has succeeded in isolating a sleep causing substance from the brains of rats. This powder hoped to be marketed by 1982, will induce a sound and natural sleep. But, according to Dr. Uchizono, the production of this sleeping powder is possible only after its molecular structure is established.

Antibiotics in animal feed

US National Research Council has told Food and Drug Administration that antibiotics in animal feed can not be scientifically linked to human health effects. Epidemiological studies have neither proved nor disapproved any hazard to human health but lack of data should not be taken to suggest that hazards do not exist. Research necessary to establish and measure definite risks has not been carried out.

PMA Newsletter, **22,** No. 14, 6 (7 Apr. 80)

Butorphanol and nalbuphine—two new analgesics

Two new strong analgesics butorphanol tartrate (Stadal; Bristol) and nalbuphine hydrochloride (Nubain; Endo) have mixed agonist-antagonist type activity with pharmacological actions resembling those of pentazocaine lactate.

Butorphanol gives satisfactory relief in moderate to severe pain in acute postoperative pains. It is comparable to morphine, meperidine (pethidine) hydrochloride and pentazocaine and its analgesic effect peaks at about half an hour and lasts for about 3-4 hours after *im* injection. It is similar to meperidine in women in labour and as a preanaesthetic medication, but causes more sedation. Its most common adverse effects are sedation, nausea and sweating. It is contraindicated in patients on opiates and those having respiratory depression.

Nalbuphine has about the same potency as morphine and antagonistic potency about 10 times greater than pentazocaine. Its action starts 2-3 minutes after *iv* administration, or 15 minutes after *im* or *sc* administration and lasts for 3-6 hours. It relieves moderate to severe pain (postoperative trauma, cancer). Its adverse reactions are same as those of morphine and other strong analgesics.

Inpharma, No. **234,** 3 (26 April 80).

C. R. M. Proposes guidelines on benzodiazepines

The UK Committee on the Review of Medicines has issued certain guidelines for the therapeutic use of benzodiazepines. Emphasis has been placed on (*a*) Indications other than anxiety and insomnia and the long-term use of benzodiazepines, (*b*) Residual effects (day time sedation etc.), (*c*) Possible dependence and withdrawl symptoms; and (*d*) The implication for clinical use, especially in the elderly.

Differences between long acting (half life more than 10 hours) benzodiazepines such as clorazepate, diazepam, chlordiazepoxide and medazepam and the short acting ones such as triazolam, temazepam, oxazepam and lorazepam have been highlighted. The later group has rapid excretion, no accumulation and is advantageous in elderly patients, and in those having renal and hepatic impairment. All benzodiazepines are useful in anxiety and insomnia. They may be given in muscular spasm, acute alcohol withdrawal, and night terrors and somnambulism in children. But for the treatment of depression, tension headache, dysmenorrhea, psychotic illness or anxiety and insomania in children they seem to be unsuitable and lose their effectiveness on continuous use over 3-14 days. Habitual and long term use of diazepam and similar benzodiazepines can lead to dependence and other adverse effects. Withdrawal may give rise to anxiety, apprehension, tremor, insomnia, nausea, and vomiting and appear 3-10 days after withdrawl of long acting drugs and within 24 hours of the short acting ones. Clinically, withdrawal symptoms resemble symptoms of original illness thus resulting in the restart of the treatment. Residual daytime sedation with long acting drugs leads to drowsiness, impaired co-ordination and judgement. Adverse reactions increase in elderly and are accompanied by confusion.

Inpharma, No. **232,** 11 (12 April 80)

Headache: the different ways to treat it

Headache can be a manifestation of pathological disorders and is usually primary. It falls into 3 main categories: tension headache, vascular headache (including migraine) and cluster headache. If all features are consistent with primary headache, further diagnostic tests are not needed. It they are highly focal, persistent and of recent onset, with other abnormal findings then further inquiry is essential.

The treatment of primary headache has two main objectives symptomatic relief, or prophylaxis to reduce frequency/severity. Pharmacological measures should only be adopted when other methods like education, counselling, reassurance, or even formal psycotherapy fail.

Mild moderate tension and vascular headache can be cured by non-narcotic analgesics, may be in combination with caffeine (for vasoconstriction) and a mild sedative: aspirin, propoxyphene (Dextropropoxyphene), ibuprofen, phenacetin or acetaminophin combinations. Eighty per cent of the vascular headaches are treated by ergotamine tartrate, a potent vasoconstrictor. It should be taken early in an attack but is contraindicated in peripheral vascular disease, pregnancy and hypertension. Unresponsive headaches may respond to chlorpromazine. Narcotic analgesics should be avoided.

When headaches are frequent and severe daily treatment is needed.

Diazepam and tricyclic antidepressants (e. g. amitriptyline) or β-blockers (e. g. propranolol) or the antihistamine cyproheptadine may be effective. Chlorpromazine may cure severe paroxysmal vascular and cluster headaches.

Inpharma, No. **231,** 2 (5 April 80)

MYC 2095: a long acting corticosteroid

MYC 2095 is a new corticosteroid developed by Gist-Brocades, Holland for intra-articular injection for rheumatic conditions. This long acting 21-isonicotinic acid ester of corticosteroid was given as intra-articular injection to 50 patients with gonarthritis (synovitis of the knee) in a dose of 1 ml of 2% MYC 2095, 1 ml 2% triamicinolone hexacetonide or 1 ml placebo (MYC 2095 solvent). Ten patients became symptom-free on the first injection and were excluded from the second cross-over injection a week later. The order of effectiveness in relief of symptoms after the first injection was MYC 2095 > triamcinolone > placebo. After the second injection the improvement was significant. No untoward reactions were seen.

Inpharma, No. **230,** 13 (29 March 80)

Mepindolol: a non-selective β-blocker

Mepindolol (Sandoz; SHE-222, Schering AG), a non-selective β-blocker with slight intrinsic stimulation and membrane stabilizing activity, was administered to ten patients suffering from angina pectoris. Each was given 2.5 mg *bid* orally for 4 weeks. A significant reduction in anginal attacks from 6.57 to 2.57 weekly, nitroglycerin (glyceryl trinitrate) consumption from 2.4 to 1.6 weekly and heart rate from 72 to 64.7 beats/minute occurred. In 20 hypertensive patients, 10 mg *bid* was compared with placebo in a similar cross-over trial. Supine BP dropped from 77 to 62.5 beats/minute. Standing BP and heart rate were similarly affected.

Inpharma, No. **230**, 12 (29 March 80).

Lederle to market new wide-spectrum antibiotic

Lederle will introduce next year a new wide-spectrum semisynthetic antibiotic, piperacillin. It is effective against organisms that cause illnesses ranging from peritonitis to endocarditis, pneumonia, septicemia and complicated urinary tract infections. Piperacillin is an injectable third generation penicilin and its effectiveness ranges from gram positive, gram negative to anaerobic organisms.

American Pharmacy, No. **20,** 42 (Jan. 80)

Urokinase produced by genetic engineering

Abbott Laboratories have announced the successful production of urokinase using recombinant DNA techniques. Dr. Paul Hung, leader of the Abbott team has isolated the RNA sequence for urokinase from human kidney cells. The urokinase gene is then synthesised by reverse transcription and spliced into the *E. coli* genome.

Abbott claims the urokinase produced by this technique to be as effective as produced by tissue culture or urine extraction technique but is more efficient than both. However, further research and development is needed to make the process commercial.

Scrip, No. **480,** 15 (16 April 80)

Vitamin E therapy for premature babies

National Eye Institute, Bethesda, Maryland, USA is supporting a study in which 650 infants born prematurely at 36 weeks' gestation, or less, will be given high doses of Vitamin E so as to reduce the incidence and severity of retrolental fibroplasia in them. The study aims to maintain Vitamin E serum levels of 5-7 mg/dl until the eyes are matured or as long as there is active retrolental fibroplasia. This will be achieved by grouping the infants accord-to birth weight and randomly assigning treatment with Vitamin E (dl-α-tocopherol) or placebo.

The premature infants when given excessive oxygen therapy develop retrolental fibroplasia. Also it has recently been established by animal studies and a study of small number of infants that those born premature are deficient in Vitamin E. Vitamin E protects cell membranes from damage by oxygen. Larger clinical trials are in progress. Another use of Vitamin E proposed by some Canadian researchers is in possible prevention of cortical cataracts in diabetic patients. According to them, the Vitamin may reduce precataractous formation of globules due to increased blood glucose levels and may also render membranes of the cortex of the lens more flexible. This has been shown by *in vitro* and *in vivo* studies on rat lenses. The studies are now being extended to lower primates.

Inpharma, No. **230,** 3 (29 March, 80)

REGULATORY NEWS

Import Policy for 1980-81 announced

Mr. Pranab Mukerjee, Union Minister of Commerce and Civil Supplies announced the import policy for 1980-81 on 15 April. D. D. T. import will be canalised henceforth. Amidopyrine, 6-APA, ampicillin sodium, chloramphenicol, sodium succinate, chloroquin sulphate, erythromycin ethyl succinate, ethoxymethylene di-methylmelonate, novaldiamine and TIOC imports have been decanalised. Of these amidopyrine, and Vitamin C, Vitamin B_{12} imports have been banned. The essential details of the policy pertaining to drugs and pharmaceuticals are as under:

Items taken out of OGL in 1980-81 and placed in the restricted list

- Mephensin (glyceryl ortho cresyl ether)
- Potassium guiacol sulphonate (Thiacol/ potassium sulfoguiacolate)
- Light magnesium oxide
- Sodium dichromate
- Potassium dichromate
- Basic chromium sulphate
- Cetrimide
- Chlorhexidine-base
- Tetramisole hydrochloride
- Primidone
- Halothane
- Sodium chlorite
- Methyl anthranilate
- Inositol
- Parachloro aniline
- De-methyl chloro-tetracycline
- Endosulfan
- Alpha naphthalene acetic acid

Items taken out of OGL and placed in the banned list

- Paraphenetidine
- Methapyrilene and its salts
- Isonicotinic acid
- Nocotinic acid
- Nicotinamide

(This list does not contain items that might have been taken out of OGL as a result of amendments to the descriptions of entries in Appendices 3, 5, etc.)

Items going into the banned list in 1980-81 Policy—1979-80 Policy is given in brackets

- Paraphenetidine (OGL)
- Methapyrilene and its salts (OGL)
- Isonicotinic acid (OGL)
- Nicotinic acid/nicotinamide (OGL)

Amidopyrine (canalised)

Lanolin anhydrous/adeps/lanae/wool fat (all grades except pharmaceutical grade) (restricted),
Caffeine and its salts (restricted)

3:3 dichloro benzidine dihydrochloride (restricted)

Vitamin C (canalised)

Vitamin B_{12} (canalised)

This list does not contain items that might have gone into the banned list as a result of amendments to the descriptions of certain entries in Appendix 3.

Items taken out of the banned list in 1980-81 and placed in restricted list

Succinyl succinate

Maleic anhydride

Cocoamine

Phthalic anhydride

Dimenhydrinate

Para toluene sulphonyl chloride

Sulphanilic acid

Dichloro acetic acid

Meta-di-nitrobenzene

Turpentine oil

New item included in canalised list

Griseofulvin

Items removed from canalised list

Amidopyrine

6-APA

Ampicillin sodium (now under OGL)

Chloramphenicol stearate and chloramphenicol sodium succinate

Chloroquin sulphate

Erythromycine ethyl succinate

Ethoxymethylene di-methylmalonate

Novaldiamine (now under OGL)

TIOC

"All Vitamins"

Vitamins included in the canalised list

(*i*) Vitamin B_1

(*ii*) Vitamin B_2

(*iii*) Vitamin D_3

(*iv*) Rutin

(*v*) Vitamin E acetate

(*vi*) Menadione

(*vii*) Menadione—Sodium bi-sulphite and Aceto menadione

Anti-malaria steps advised

The Union Health Secretary, Mr. Kirpa Narain, in a letter addressed to the Secretaries of the Ministeries of Energy, Irrigation, Industry, Defence, Agriculture and the Chairman Railway Board, has asked them to make adequate arrangements for the controlling of incidence of malaria in major industrial projects. According to this communication, both during the construction phase and the maintenance phase of any major project, interstate movement of a large labour force takes place, some of which is from highly endemic malarious areas. This has resulted in many serious outbreaks of malaria in some of these projects and many casualities have also been reported. Efforts should be co-ordinated in such a way that these outbreaks are controlled.

Cash compensatory support for chemicals and allied products announced

The Union Government has revised cash compensatory support for a wide range of chemicals and allied products from April 1. Alums will get 7.5 per cent assistance for 1980-81. Carbon black 7.5 per cent for 1980-82. Ayurvedic, Unani and Siddha Medicines, 20 per cent for 1980-82. Calcium chloride and glucose which were getting a subsidy of 5 per cent will now get 2.5 per cent for 1980-81. Certain chemicals for which rates will remain same up to March 31, 1981 are: magnesium chloride 5; sodium bicarbonate 5; sodium sulphate, 7.5; aluminium chloride, 7.5; sodium silicate, 5; ammonium chloride, 5; and emulsifers and de-emulsifers, 5 per cent.

Gujarat High Court: Anaesthetics, tranquillisers are not narcotics

The Gujarat High Court while disposing off the petition filed by Sarabhai Chemicals and Suhrid Geigy, has ruled that local anaesthetics and tranquillisers are not narcotics within the definition of section 2 (H) of the Medical and Toilet Preparations act of 1965 and excise duty is not applicable to them on the basis that they contain narcotics.

The firms had contested that the Central Government was already levying and collecting excise duties under Central Excise and Salt Act of 1944 on these preparations under item 14-E as medical and toilet preparations not containing narcotics. The court agreed with the firms' submission that unless the preparation is likely to lead to insensibility it could not be said to be narcotic simply because it was apt to produce drowsiness or sleep.

States asked to continue BCG vaccination

The Union Health Minister Mr. B. Sankaranand, has asked all the State Governors and Chief Ministers to continue with BCG vaccine for immunising infants against tuberculosis. According to him, BCG does provide a measurable degree of protection against primary infection of tuberculosis.

Doubts about the efficacy of BCG were raised when a large scale clinical trials in Chingleput district of Tamil Nadu showed that it offers no protection against lung turberculosis in adults.

Six drugs reserved for small sector

The Union Government has reserved the production of six simple technology involving drugs for small scale sector only. The drugs are glycero-phosphate, glycerophosphoric acid, paracetamol, lanolin, anhydrous citrates and tartrates. The Planning Commission has estimated, on the basis of the report of its working group on drugs and pharmaceuticals, that as a result of measures taken by the government, the small scale sector will achieve an annual growth rate of 19.5 per cent in the current five year plan.

The government is extending to the small scale drug units the preferential treatment given to all small scale industrial units as a matter of general policy. Raw material allotment to such units will also be liberalized. Units with annual turnover of less than Rs. 1 crore are entitled to 50 per cent growth rate in the allocation of raw materials and those exceeding 1 crore are entitled to 25 per cent growth rate. The policy of granting the benefit of past consumption has been liberalised in the case of small drug units.

It has also been decided to abolish the trade names for single ingredient drugs so that small drug units become entitled to produce these items. Experience gathered from this will be a guiding force for any extension in this policy. Regarding the complaints of shortage of some vital drugs remedial measures are being taken. Shortfall is attributed to power failures, industrial unrest and non-availability of some basic raw materials and this is affecting whole of the industrial sector. Drug industry is facing problem in getting caustic soda, ethylene oxide etc.

Drug firms may be granted CTC exemption in UK

Mr. Patrick Jenkin, UK Secretary of State for Health and Social Services has announced that the British government will shortly introduce a new scheme under which drug companies will be able to apply for exemption from the need for a Clinical Trial Certificate. This will enable them to conduct limited short term clinical studies at an earlier stage than is currently possible.

This is one of the two proposed methods of encourging clinical trials in UK, the other being the Prof. David Grahame-Smith working party's study of ways of reducing pre-CTC toxicity testing requirements.

Scrip, No. **481,** 2 (19 April 80)

Foreign stability tests to be acceptable in Japan

The Japanese Ministry of Health & Welfare has announced that to help promote international pharmaceutical trade, it will accept foreign chemical and physical stability data. For this new standards are being set-up. The new drug stability tests will have to conform to typically Japanese temperature and humidity conditions under which long term stability tests must be conducted. Duration of these tests is also being extended from 2 to 3 years in accordance with the revised requirements for duration of efficacy as laid down in Japanese Pharmaceutical affairs laws.

Scrip, No. **482,** 13 (23 April 80)

FDA refuses approval to anturane

The US Food and Drug Administration has announced that anturane used as a gout remedy and also reported to be useful in reducing sudden deaths after heart attacks will not be approved for use in heart condition (*See* This bulletin Vol. 3, No. 3, p. 70). The tests supporting this claim are inconclusive, FDA says.

PMA Newsletters, **22,** No. 17, 6 (28 April 80)

Mestranol in oral contraceptives banned

The Israeli drug authorities have banned oral contraceptives containing more than 50 microgram of mestranol, effective from 1 January 1980. Possible carcinogenic effect is the reason behind this ban.

ABPI News, No. **178,** 5 (Dec. 79)

Philippine drug firms to appoint medical directors

Philippines Ministry of Health has asked the drug companies to appoint a medical director who should be responsible for introducing and marketing any new drug. This is to ensure the efficacy of drugs for the benefit of the buying public.

ABPI News, No. **178,** 5 (Dec. 79)

KARNATAKA STATE DRUGS CONTROL DEPARTMENT

(*Monthly Report:* February 1980)

During this month, the Drugs Control Department granted three licences for manufacturing biological drugs and four for non-biological drugs. Similarly 432, 587 and 9 establishments were given licences to sell biologlcal, non-biological and homoeopathy drugs respectively.

The department carried out inspections of 8 manufacturing, 407 sales and 16 hospital premises. 42 inspections were carried out under Drugs (Prices Control) Order.

Manufacturing and drugs sales establishment were checked for malpractices. One licence was suspended, 15 cancelled, 52 invalidated and 25 licencees were warned. Three prosecutions were launched under Drugs and Cosmetics Act. Two contraventions were detected out of 430 advertisements scanned under Drugs & Magic Remedies (Objectionable Advertisement) Act.

INDUSTRIAL LICENCES

ISSUED DURING JANUARY AND FEBRUARY 1980

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type and No. of Licence
1.	The Bengal Immunity Co. Ltd. Immunity House, 159, Lenin Saranee, Calcutta-700 013.		Magnesium hydroxide cake	7.5 tonnes	New Article
			Cholic acid	240 kgs	
			Dehydrocholic acid	120 ,,	
			B. I. diastase powder	700 ,,	
			Ox-bile extract	480 ,,	
			Phthalyl sulphacetamide	300 ,,	
			Aminoacridine sulphadiazine Aminoacridine hydrochloride	18 ,,	
			Sulphanilyl benzamide	3 tonnes	
			B. pertussis	60 litres	
			B. I. Omnigen	1000 ,,	
			TAB vaccine	500 ,,	
			TAB cholera vaccine	3000 ,,	
			Cholera vaccine	6000 ,,	
2.	Indian Dairy Corporation, 'Darpan' R. C. Dutt Road, Baroda-5.	Gachhibowli, K. V. Rangareddi, Hyderabad (A. P.)	Foot and mouth disease vaccine	25 million quadrivalent doses	New Unit CIL: 54/80 dated 27.2.80
3.	Karnataka Antibiotics & Pharmaceutical Ltd., C/o Hindustan Antibiotics Ltd. Pimpri, Pune-411 318.	Kadabgere Taluka: Nelamangale, Bangalore (Karnataka)	Streptomycin sulphate 1 g	170 lakh vials	New Unit CIL: 15/80 dated 18.1.80
			Streptomycin sulphate 0.75 g	10 ,, ,,	
			Sodium ampicillin 0.5 g	30 ,, ,,	
			Sodium ampicillin 1 g	30 ,, ,,	

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type and No. of Licence
			Vitamin C injection 1 ml (110 mg/ml)	20 lakh ampoules	New Unit CIL: 36/80 dated 1.2.80
			Vitamin C injection 2 ml (100 mg/ml)	10 ,,	
			Vitamin C injection 1 ml 500 mg	3 ,,	
			Gentamycin injection 2 ml vial (40 mg/ml.)	10 ,,	
			Kanamycin injection 0.5 g per vial 2 ml	3 ,,	
			Kanamycin injection 1 g vial 2 ml	3 ,,	
			Erythromycin injection 2 ml	38.3 ,,	
			Ampicillin capsule 250 mg	38 ,,	
			Chloramphenicol capsule 250 mg	200 ,,	
			Rifampicin capsule 150 mg	10 ,,	
			Cloxacillin capsule 250 mg	10 ,,	
			Amoxycillin capsule 200 mg	20 ,,	
			Doxycycline capsule 100 mg	50 ,,	
			Penicillin V 125 mg	15 ,,	
			Penicillin V 250 mg	5 ,,	
			Vitamin C 100 mg	700 ,,	
			Vitamin C 500 mg	100 ,,	
			Erythromycin 250 mg	50 ,,	
			Neomycin	7 ,,	
			Folic acid 5 mg	800 ,,	
			PAS sodium 500 mg	30 ,,	
			INH 50 mg	150 ,,	

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type and No. of Licence
			INH 100 mg	80 lakh ampoules	
			Analgin 500 mg	44 ,,	
			Sulphadimidine 500 mg	40 ,,	
			Piperazine adipate 300 mg	40 ,,	
			Ethambutol 200 mg	101 ,,	
			Chloroquin phosphate 200 mg	150 ,,	
			Chlorpromazine HCl 25 mg	15 ,,	
			Metronidazole 20 mg	30 ,,	
			Metronidazole 100 mg	10 ,,	
			Aminophyline 100 mg	40 ,,	
			Digisine diastase enzyme 200 mg	40 ,,	
			Multivitamin 500 mg	25 ,,	
			Antacid tablets 1 mg	71 ,,	
			Antiasthmatic 250 mg	25 ,,	
			Mebendazole 100 mg	10 ,,	
			Rifampicin 150 mg	1 ,,	
			Streptopenicillin 1/2 mg (injection)	20 lakhs vials	
			Fortified procaine penicillin	20 lakhs tablets	
4.	Searle (India) Ltd., Ralli House, 21, Ravelline Street, Bombay-400 001.		Gama benzene hexachloride	1 tonne	New Article CIL: 26/80 dated 23.1.80
			A. *Tablets:*		
5.	Smith Stainistreet Pharmaceuticals Ltd., 18 Convent Road, Calcutta-14.	Calcutta	Phenoxymethyl penicillin potassium 250 mg	10.0 million nos	New Article CIL: 53/80 dated

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
	18, Convent Road,		Salbutamol 2 mg	2.0 million nos	22.2.80
	Calcutta-14.		Salbutamol 4 mg	2.0 ,,	
			Diazepam 5 mg	20.0 ,,	
			Nitrazepam 5 mg	5.0 ,,	
			Glybenclamide 5 mg	2.0 ,,	
			Pheniramine maleate 25 mg	100.0 ,,	
			Pheniramine maleate 50 mg	25.0 ,,	
			Cholrpheniramine maleate 4 mg	150.0 ,,	
			Iodocycline forte containing in each : Quiniodochlor 200 mg, Chloroquin phosphate 80 mg, Tetracycline hydrochlor 167 mg	20.0 ,,	
			Pentrosol containing in each : Phenoxymethyl penicillin 65 mg Sulphadiazine 170 mg Sulphamerazine 170 mg Sulphadimidine 170 mg	30.0 ,,	
			B. Oral suspension:		
			(*i*) Pengol syrup containing 125 mg phenoxymethyl penicillin potassium per 5 ml	1.0 million nos	
			(*ii*) Chloramphenicol streptomycin syrup containing 125 mg each per 5 ml		
			30 ml bottle	1.0 ,,	
			60 ml bottle	1.0 ,,	

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type and No. of Licence
			C. *Injections:*		
			(*i*) Gentamycin 40 mg per ml, 1.5 ml	2.0 million nos	
			Ampoule/vial 2 ml	2.0 ,, ,,	
			D. *Syrup:*		
			(*i*) Salbutamol 2 mg per 5 ml 100 ml bottle	0.5 ,, ,,	
			(*ii*) Zip cough syrup forte-each 5 ml to contain:		
			Chlorpheniramine maleate 2 mg		
			Ephedrine hydrochlor 4 mg		
			Noscapine 12 mg		
			Ammonium chloride 30 mg,		
			Sodium citrate 40 mg		
			Chloroform 0.013 ml		
			Alcohol less than 3% V/V		
			50 ml bottle	2.0 ,, ,,	
			100 ml bottle	2.0 ,, ,,	
			450 ml bottle	2.0 ,, ,,	
			(*iii*) Zip expectorant-each 5 ml to contain: Chlorpheniramine maleate 2 mg, Ammonium chloride 115 mg		
			Sodium citrate 50 mg,		
			Menthol 1 mg,		
			Alcohol less than 3% V/V		
			50 ml bottle	2.0 ,, ,,	
			100 ml bottle	2.0 ,, ,,	
			450 ml bottle	2.00 ,, ,,	

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type and No. of Licence
6.	State Industrial & Investment Corpn. of Maharashtra Ltd., 1st Floor, Nirmal, Nariman Point, Bombay-400021.		*Bulk Drugs:*		
			Chloroquin phosphate	50 tonnes	New Unit LI: 38/80 dated 21.2.80
			Theophylline & Aminophylline	60 ,,	
			Ephedrine hydrochloride	30 ,,	
			Xylocain	20 ,,	
			Dapsone	30 ,,	
			Formulations: Single bulk drugs (not involving other bulk drugs) as under:		
			(*i*) Chloroquin phosphate (*ii*) Aminophylline (*iii*) Ephedrine Hydrochloride (*iv*) Dapsone	Corresponding to 35 per cent production of xylocain and 70 per cent production of other bulk drugs.	
7.	Suhrid Geigy Limited, P. B. No. 48, Wadi Wadi,		Parazolandin	250 lakh tablets	New Article CIL: 7/80 dated 11.1.80
8.	Synbiotics Limited, Post Box No. 129, Wadi Wadi, Baroda-390 007.		Streptomycin Sulphate	80 tonnes (existing) 170 tonnes (after expansion)	Substantial expansion CIL: 3/80 dated 5.1.80
9.	Unichem Laboratories Ltd., S. V. Road, Jogeshwari Bombay-400060.	Roha Distt. Colaba (Maharashtra)	Duracyclin syrup	5 lakh bottles (30 ml each)	New Article CIL: 33/80 dated 1.2.80
10.	West Bengal Pharmaceutical and Phytochemical Development Corporation Limited, 1 and 3 Brabourne Road, Calcutta.		Aspirin I P	1,000 tonnes	New Unit LI: 4/80 dated 9.1.80

NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
1.	*Analgesic*			
	Diflunisal	Dolobid	Merck Sharp & Dohme	Malaysia/ Singapore
	Glafenine	Glafedol	Regent	Philippines
2.	*Analgesic/Tranquillizer*			
	Acetaminophen + chlormezanone	Neo-beserol	Winthrop	Philippines
	Paracetamol+ chlormezanone	Myoflex	Lennon	S. Africa
3.	*Androgen*			
	Testosterone undecanoate	Andriol	Organon	Malaysia/ Singapore
4.	*Anthelmintic*			
	Oxantel pamoate+ pyrantel pamoate	Quantrel	Pfizer	Malaysia/ Singapore
5.	*Antianginal*			
	Lidoflazine	Clinium	Janssen	UK
6.	*Antibacterial*			
	Amikacin	Biklin	Bristol	Sweden
	Cefatrizine	Briceph	Bristol Meyers	Japan
		Cepticol	Banyu	Japan
	Cefuroxime	Ceroxime	Glaxo	France
	Dibekacin	Panamicin	Gerardo Ramon	Argentina
	Fosfomycin	Veramina	Roux-Ocefa	Argentina
	Josamycin	Josacine	Spret-Mauchant	Switzerland
	Sesomicin	Ensamycin	Schering Corp	Malaysia/ Singapore
	Trimethoprim + sulphadiazine	Trimin	Astra	Sweden

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
7.	*Antihyperlipidemic*			
	Benzafibrate	Bezalip	Boehringer Mannheim	Malaysia/ Singapore
8.	*Antihypertensive*			
	Guanabenz	Rexitene	Wyeth	Italy
	Metipranolol+ thiabutazide	Torrat	Boehringer Mannheim	Malaysia/ Singapore
	Minoxidil	Loniten	Upjohn	UK
9.	*Anti-inflammatory*			
	Fentiazac	Donorest	Wyeth	Malaysia/ Singapore
	Flurbiprofen	Froben	Boots	France/ Japan
	Indoprofen	Flosint	Farmitalia	Philippines
10.	*Antimalarial*			
	Sulphamethopyrazine+ pyrimethamine	Metakelfin	Farmitalia	Philippines
11.	*Antimanic*			
	Lithium carbonate	Liskonum	Smith Kline & French	UK
12.	*Antineoplastic*			
	Ftorafur	Futraful	Taiho	Philippines
	Vindesine	Eldesine	Lilly	France
13.	*Antipsychotic/antiulcer agent*			
	Sulpiride	Dogmatil	Delagrange	Malaysia/ Singapore
		Dogmatyl	Fujisawa	Philippines
14.	*β-Blocker*			
	Sotalol	Sotacor	Bristol	Sweden
15.	*β-Blocker/diuretic*			
	Sotalol+ hydrochlorothiazide	Sotazide	Bristol	UK
16.	*Bone calcium regulator*			
	Etidronate	Didronel	Proctor & Gamble	Switzerland

Contd.

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
17.	*CNS stimulant*			
	Pemoline	Ronyl	Rona	Malaysia
18.	*GI regulator*			
	Metoclopramide	Primperan	Delagrange	Malaysia/ Singapore
19.	*Labyrinthine suppressant*			
	Cinnarazine	Purazine	Lennon	S. Africa
20.	*Topical antifungal*			
	Isoconazole	Travogen	Schering AG	W. Germany
21.	*Topical corticosteroid/antimicrobial*			
	Dexamethasone+ clotrimazole+ azidamfenicol	Baycuten	Bayer	Philippines
22.	*Tranquillizer*			
	Tiapride	Tiapridal	Delagrange	Malaysia/ Singapore

MEETINGS/SEMINARS

International Pharmacy Education Congress

American Association of Colleges of Pharmacy is organising an International Pharmacy Education Congress in Boston from July 17-20, 1980. Further information can be had from:

4630, Montgomery Avenue,
Suite 21, Bethesda,
Maryland, 26014,
USA.

ABPI News, No. **178,** 4 (Dec. 79)

BOOK REVIEW

WHO Handbook for reporting results of cancer treatment

World Health Organization, Geneva 1979 (*WHO Offset Publication No. 48*) Pages 45. Price Sw. fr. 6.

During the last few decades a rapid and continuous increase in the number of investigations on cancer therapy has resulted in an enormous expansion of literature on cancer. These investigations carried all over the world are frequently reported in a way which makes it difficult for investigators to compare their results with those of others. Therefore it has become necessary to develop a "common language" to describe cancer treatment and to agree on internationally acceptable general principles for evaluating data.

This handbook is the outcome of two meetings of international groups of experts on the standardization of reporting the results of cancer treatment. The various chapters deal with the minimum sets of data required on the characteristics of patients and tumours; the reporting of treatment according to the method or methods used, singly or in combination; the recording of any significant toxic effects of treatment, a 5-grade classification being recommended; tumour measurement and the reporting of objective and subjective response to treatment; definition and recording of recurrence, and the classification of cases; and determination and calculation of the results of therapy.

It is hoped that this handbook will not only contribute to a better evaluation of the results of cancer treatment at the population and hospital levels and in studies by cancer site but will also provide individual clinicians throughout the world with a standard set of criteria for judging and reporting their results.

□

World Health Statistics Annual, 1979 —Infectious Diseases: Cases

World Health Organization, Geneva, 1979: Pages 242. Price: Sw. fr. 32.

The title *World Health Statistics Annual* was introduced in 1965 for the series previously published as *Annual Epidemiological and Vital Statistics*. From 1965 to 1978 it has provided statistical data published in three volumes:

Volume I: Vital Statistics and Causes of Death, Volume II: Infectious Diseases: Cases, Deaths (up to 1977), and Vaccinations (up to 1976), and Volume III: Health Personnel and Hospital Establishment.

The 1979 issue of *Infectious Diseases: Cases* contains statistical data for 1975, 1976 and 1977 which complete the statistical series for some countries.

The information has been obtained from various sources such as,

(1) World Health Organization questionnaires sent out to Member States,

(2) Annual reports or other publications of national health administrations,

(3) Periodic (weekly, monthly or quarterly) reports sent to the World Health Organization by national public health services.

The data thus collected are published in three tables giving,

annual figures for morbidity by countries,

seasonal distribution of cases, by months or four-week periods, and

breakdown of cases by sex and age.

□

The selection of essential drugs

Second report of the WHO Expert Committee. *World Health Organization Technical Report Series*, No. 641, 1979 Pages 44 Price: Sw. fr. 3.

The model list of essential drugs presented in this second report of the WHO Expert Committee on the Selection of Essential Drugs is a revised and updated version of the list included in the first report, issued in 1977. The original list was circulated for comment to all members of the WHO Expert Advisory Panels on Drug Evaluation and on the International Pharmacopoeia and Pharmaceutical Preparations, to the WHO regional offices, to national health authorities, and to interested international and non-governmental organizations. Their comments, and many unsolicited comments arising from the great interest caused by the publication of the first list, were considered by the Expert Committee in the summer of 1979.

A feature of the Expert Committee's revised list, which did not appear in the former version, is a selection of dosage forms and strengths, of which the purpose is to identify the most appropriate pharmaceutical forms and to advise countries wishing to standardize or minimize the number of preparations in their own drug lists. As a general rule, pharmaceutical forms have been selected on the basis of their general utility and their wide availability internationally. No changes have been made to the original model list unless definite advantages are considered to accrue from them. Immediately following the list is a detailed review of the amendments that have been made, together with the rationale for each change.

At the end of the report the Expert Committee emphasizes the importance of exchanging information on essential drugs, both with national agencies and with the pharmaceutical industry and suggests how to set about this task, the aim being to ensure the availability of the most appropriate and economical pharmaceutical forms to meet the health needs of developing countries.

The report once again makes it clear that the list is intended as a model from which countries can develop their own national lists of essential drugs; it is no way mandatory, nor is it proposed as universally applicable.

□

DRUG INDUSTRY

General News

Export of drug formulations declines

Export of drug formulations has gone down to Rs. 21.06 crore in 1979-80 compared to Rs. 27.18 crore during 1978-79. Of the various reasons attributed to this shortfall, two are: 1) non-availability or shortage of production of many bulk drugs leading to less production of formulations for export; (b) setting-up of production units for formulations in importing countries itself.

India exports formulations mainly to the developing countries of Africa, South East Asia, West Asia and USSR. But now the trend in these countries has changed as they have started buying basic drugs used in formulations. India could export basic drugs worth Rs. 11.56 crore in 1979-80 against Rs. 11.62 crore in the year 1978-79.

India's share in world export is hardly one per cent of the World's total, but this could be increased by adopting certain measures as suggested by the working group on drugs and pharmaceuticals appointed by the Government of India. The group has suggested that manufacturing facilities under loan licence system should be allowed to be utilised by the manufacturer/exporter to enable them to execute the export orders expeditiously. Further, cash incentives in respects of certain drugs having good export potential should be reintroduced.

UNDP aided centre for drug industry to be set up at Hyderabad

The Government is planning to set up a pharmaceutical industry development centre at Indian Drugs & Pharmaceuticals Ltd. complex at Hyderabad. The Centre is a collaboration project with UNDP, which will be providing financial assistance of $1.66 million. The equipment available at IDPL will be used for the study of operational problems of the industry.

The aims and objectives of the centre will be: a) Manpower and technical skill development through training courses on various stages of drug production; 2) Study of operational problems in production; and 3) Systematisation of methods and techniques of operating pharmaceutical plants. Besides the centre is also expected to provide assistance to individual small scall units in conducting stability, toxicological and bioavailability tests and in products formulations and process development.

Initially the centre will train the personnel sponsored and/financed by drug industry but afterwards it will be expanded into a regional centre for South-East Asia and candidates from other third world countries would be accepted.

Indo-Bulgarian move to promote joint ventures in third countries

India and Bulgaria have agreed to discuss the possibilities of setting up joint ventures in third countries, in the fields of petroleum, chemicals and petrochemicals. This was decided at a meeting—the fifth in series—of the sub-commision for chemicals and Pharmaceuticals industry held at Delhi. This decision is within the scope of Indo-Bulgarian joint Commission for Economic, Scientific and Technical Co-operation. Experts from both the countries are expected to meet in September-October this year either at New Delhi or at Sofia to discuss specific proposals in this regard.

Foreign drug companies profits found reasonable

A committee set up by the Government in May 1978, following the recommendations of the New Drug Policy to investigate allegations of unduly large profits made by foreign drug companies has found that nearly two-third of them have an average post tax return of 14% in the last ten years in their total manufacturing activity. Only in the case of three companies the average post tax return was above 20%, considered exceptionally high. On the whole the committee, headed by the Chairman of the Bureau of Industrial Costs and Prices, has found the profitability of foreign pharmaceutical companies at a level which can not be considered excessive. Other important findings of the committee about the activities of foreign drug companies are: their profitability comparing favourably with that realised by the more profitable industrial sectors in India; the proportion of expenses on account of over-heads, sales promotion, etc. as 33% of total costs, which is substantially higher than in other industries; research and development expenditure only 0.83% of total costs, except in case of two companies.

The committee has recommended setting up of a research group in the Union Ministry of Petroleum, Chemicals and Fertilizers or at the Bureau of Industrial Costs and Prices to study continuously import prices, identify serious anomalies and seek clarifications from importing drug companies and determine the cost-effective methods of arranging such imports.

New drugs to be produced with foreign collaboration

According to Mr. Veerendra Patil, the Minister for Petroleum and Chemicals India has signed technical collaboration projects with some foreign companies to produce drugs which are not already being made in the country. Gentamicin sulphate will be produced under an agreement between Hindustan Antibiotics Ltd., Pune and Medimpex and the Chinoin Chemical & Pharmaceutical Works Ltd. of Hungary. IDL Chemicals Ltd., Banglore has collaborated with Astra of Sweden for the manufacture of terbutaline sulphate, prilocaine hydrochloride, iron/sorbitol complex, isosorbide dinitrate and xylocaine. Sunil Synchem, Alwar and BTB Industria Chemica SPA, Milan (Italy) have collaborated to manufacture methyldopa.

Drug industry resents switch over to generic names

The Government notification requiring the drug industry to change over to generic names has become a bone of contention between the industry and the Government.

The drug manufacturers were so far required to print brand names and generic names of drugs in an equally prominent manner on the labels, as per the Drugs and Cosmetics Rules. This in no way harmed the brand image of the product. But the present move of giving prominence to generic name is believed to seriously undermine the brand name. Drug industry fears that it may be a forerunner of the Government's future plan to totally abolish the brand names on formulations. Industry associations like Organisation of Pharmaceutical Producers of India and Indian Drug Manufacturers Association have strongly resented the Government move.

The drug industry associations point out that this change will lead to hardships and immense loss to the industry with no benefit to the consumer. It will involve an additional sum of Rs. 5 crore for redesigning and printing all packing material conforming to the amendment. There are nearly 40,000 medicines in the market today. Sources point out that generic names of drugs are generally long and printing them in a more conspicuous manner especially on vials of 5 ml or 10 ml and also on small bottles along with a number of other particulars is quite impossible. For example, "Potassium phenoxymethyl penicillin" is a much longer word than its brand name "Fenocin". Similarly it will create problem for names like, "Dihydroergotamine methanesulphonate" etc. Printing proper names of active ingredients in combination products more conspicuously than the brand names is more impracticable.

The amendment by the government is a sequel to the recommendations of Hathi Committee which suggested abolition of brand names for 13 drugs as an experimental measure. The government has accepted the recommendations but has limited the brand names abolition to only five drugs namely, analgin, aspirin, chlorpromazine, ferrous sulphate and piperazine. The effect of this limited experiment is yet to be studied and assessed. The Government feels that aggressive promotion of the trade name tends to increase the cost of the drugs to the consumers.

W. German drug industry association reacts to brand name abolition

The West German BPI has submitted a memorandum to Indian Ministry of Petroleum, Chemicals and Fertilizers over the Government's decision to abolish brand names for five bulk drugs namely; analgin, aspirin, chlorpromazine, ferrous sulphate and piperazine and also for new single ingredient drugs when first introduced in India. The association while strongly opposing this step has pointed out that it will affect the industrial proprietary rights of German pharmaceutical companies and their Indian collaborators and is contrary to the provisions of Indo-W. German treaty, under which Indian Government can not as a rule nationalise or expropriate the approved foreign investments. W. German investment in chemicals and pharmaceuticals during 1978-79 was Rs. 79 crore. The six W. German drug companies currently operating in India are: Bayer (foreign equity 52.73%; 1978-79 sales Rs. 42.2 crore), Hoechst (50%, Rs. 32.3 crore), E Merck (60%, Rs. 7.5 crore), German Remedies (39.29%, Rs. 6.5 crore), Boehringer-Knoll (39%, Rs. 5.5 crore) and Roussel (33%, Rs. 6.5 crore).

The objections of W. German pharmaceutical industry listed in the memorandum are: 1) The move is discriminatory as the drugs have been selected arbitrarily; (2) This step is against the permission granted under FERA to foreign companies for the use of trademarks in India; and (3) Trade marks are acknowledged as industrial property rights and abolition of these is an indirect expropriation of W. German investment in India.

The memorandum has also pointed out that the decision not to allow brand name for a new single ingredient drug when first introduced in India, will deprive the country of the latest pharmaceutical advances as no drug company would like to introduce a new drug under a generic label.

OPPI resents 1980-81 drug distribution policy

The Organisation of Pharmaceutical Producrs of India has represented to the Ministry of Petroleum, Chemicals & Fertilizers criticising the 1980-81 distribution policy for canalised drugs and has demanded its reconsideration. The proposed allocation of canalised drugs to DGTD units, on the basis of the highest production for the three years ending March 77, completely disregards normal growth factors, according to OPPI. The policy would force DGTD units to cut down production because of the non-availability of canalised raw materials, thus aggravating the current shortage of essential drugs.

Interim price hike demanded by drug units

Organisation of Pharmaeeutical Producers of India, The Pharmaceutical & Allied Manufacturers & Distributors Association Ltd., and All India Manufacturers Organisation have jointly represented to union government to allow interim price increases for bulk drugs and formulations.

The memorandum points out that in a series of discussions with Secretary and other officials of Health Ministry, as well as with Chairman and officials of Bureau of Industrial Costs and Prices the relevant data were collected for granting a general price increase and the decision was to be notified in 4 to 5 weeks. But, so far, no action has been taken though the above meetings were held in November, 1979.

The memorandum further says that since November 1979 a significant increase in the prices of various inputs has occurred and the industry is finding it difficult to operate in a viable manner and some units have even suffered losses. Units are unable to recover their costs and this is forcing them to curtail production of essential drugs. Therefore, to maintain the level of production and adequate supplies of medicines to meet the nation's drug needs it is imperative that a price increase should be announced immediately.

Drug formulations: Strange rationale

Drug industry is in a big confusion over the Government's attempts to eliminate irrational formulations. About a year back, on the recommendations of WHO, the Government had introduced a scheme called therapeutic rationale to identify and eliminate useless drugs from the market. The WHO guidelines were however, not transmitted to the industry. Drug Controllers sent detailed questionnaires to manufacturers to identify the therapeutically useless drugs which, in fact, should have been done by a committee appointed by the Union Government on the basis of some uniform policy. As a result what was rationale in one state became irrational in the other.

According to the manufacturers, the State Drug Controllers do not brand a drug irrational but refuse licence on the grounds of suspected therapeutic use. Their decision, though, could be challenged at Drug Controller of India's office, it takes more than six months for any decision to be taken. The manufacturers feel that before declaring a formulation irrational, the drug company should be given a chance to establish the claim of rationality of the formulation.

Ethical guidelines for clinical research laid down by ICMR

The Indian Council of Medical Research has formulated a set of guidelines to protect patients and volunteers from being exposed to unjustified hazards and risks during experiments. Earlier the matter used to be left to the conscience of individual scientists or to the institutional ethical committees wherever they existed. But now for the first time a code has been drawn up at the Central level for the guidance of scientists involved in clinical research.

ICMR has urged all the medical colleges and research centres in the country to form local ethical committees which should function as watch-dogs and assess and monitor every single clinical research proposal also from the ethical point of view. Any research project involving human beings must have a prior approval of an ethical committee. These committees are intended to be independent bodies and should include experienced clinicians besides a drug expert and a few non-medical persons well-versed in matters of ethics and law.

The institutional ethical committee before allowing any experiment should check whether the researcher has the required knowledge and competence to conduct the experiment. Researcher should make sure that the risks to the patient are out-weighed by the potential benefits to him in particular and society in general. The patient or volunteer should be informed of the risks involved and his consent obtained. The volunteer should have the liberty of terminating his participation in the experiment at any stage. Regarding trials of drugs, whether developed in India or abroad, clearance from the Drug Controller of India must be obtained before presenting the proposal for the consideration of ethical committees.

Fresh investment to incease bulk drug production

Government has cleared investment proposals totalling over Rs. 100 crore to step-up the drug production in the country, especially of the bulk drugs. Present bulk drug production in the country is worth over Rs. 180 crore.

A total of 50 bulk drugs will be produced by different companies, the prominent among them being Glaxo, Pfizer, Wyeth, Abbot, Roche and Anglo French.

Some of these companies are entering the bulk drug production field for the first time and that too after the Government's decision of not allowing any expansion in formulation capacity for foreign drug units. The two Government concerns, Hindustan Antibiotics Ltd. and Indian Drugs and Pharmaceuticals Ltd., have also plans to expand the existing capacities of many bulk drugs besides manufacturing some new bulk drugs.

According to industry sources, even this investment will be inadequate to meet the country's requirements, considering the demand estimates made by the working group on drugs and pharmaceuticals. These estimates point out that by 1982-83 the country would need Rs. 460 crore worth of bulk drugs and Rs. 1900 crore worth of formulations and to meet this target a fresh investment of Rs. 370 crore will be needed.

Units registered with DGTD during April 1980

The following nine units have been registered with the Directorate General of Technical Development for the production of drugs or drug intermediates mentioned against their name:—

Sl. No.	Name and Address of the Firm	Item
1.	M/s. Bommidila Bros. Ltd., Post Box No. 100, Meghalagiri Road, Guntur (A. P.)	Crude solanesol
2.	M/s. CIPLA Ltd., 289, Bellasis Road, Bombay Central, Bombay 400 008	(*i*) Vinblastine sulphate B. P. (*ii*) Total vinca alkaloids—(Drugs intermediates) and formulations. (*iii*) DHA Acetate (*iv*) Androstonodione (*v*) Testosterone propionate (*vi*) Testosterone enanthate USP (*vii*) Methyl testosterone (*viii*) Androstonediol (*ix*) 17 α-Hydroxyprogesterone caproate (*x*) Prolyte powder (each packet 5.5 gm) (*xi*) K. Sup liquid (*xii*) Ciplazyme tablets (*xiii*) Ciplactin syrup (*xiv*) Ciplactin drops (*xv*) Norethisterone acetate B. P.

Sl. No.	Name and Address of the Firm	Item
		(*xvi*) Estradiol benzoate B.P.
		(*xvi*) Ethinyl estradiol
3.	M/s. Dabur (Dr. S. K. Burman) Pvt. Ltd., Daburgaon, Dist. Santhal Pargana, Bihar	(*i*) Mritsanjiwanisura
		(*ii*) Agnimukhchurna
		(*iii*) Anardana
		(*iv*) Ashwagandha Churna
		(*v*) Avipattikar Churna
		(*vi*) Lavan Bhaskar Churna
		(*vii*) Gangadhar Churna
		(*viii*) Chopchinyadi Churna
		(*ix*) Hingastaka Churna
		(*x*) Lavangada Churna
		(*xi*) Mahasudarshan Churna
		(*xii*) Namak Sulamani
		(*xiii*) Pushyanag Churna
		(*xiv*) Samudradi Churna
		(*xv*) Satwaryadi Churna
		(*xvi*) Shiva Shankar Pachan Churna
		(*xvii*) Sitopaladi Churna
		(*xviii*) Pan Chasakar Churna
		(*xiv*) Talisadi Churna
		(*xx*) Trifla Churna
		(*xxi*) Narayan Churna
		(*xxii*) Suraswat Churna
4.	M/s. Mehta Pharmaceuticals (P) Ltd., Amritsar	(*i*) Strychnine HCL
		(*ii*) Strychnine alkaloids (Base)
		(*iii*) Sennosides concentrate
		(*iv*) Glycyrrhizic acid
		(*v*) Ammonium glycyrrhizine
		(*vi*) Total glycosides scilla
		(*vii*) Proscillarine
		(*viii*) Styrchinine nitrate
		(*ix*) 16 DPA
		(*x*) Progestrone
5.	M/s. Nerurkar Laboratories Pvt. Ltd., 46-B, Narayan Baug, Indore 452 003	(*i*) 4, 7, Dichloroquinoline
		(*ii*) Amodiaquine HCL
		(*iii*) Probenecid

Sl. No.	Name and Address of the Firm	Item
6.	M/s. Searle (India) Ltd., Ralli House, 21, Raveline Street, Bombay 400 001	(*i*) Dicyclomine HCL (*ii*) Doxylamine succinate (*iii*) Cetylpyridinium Chloride and formulations (*iv*) Dimethylaminoethyl Chloride HCL
7.	Shri T. G. Patel (M/s. Reela Chemicals Industry (P) Ltd. Ankleshwar	Oxyphenbutazone
8.	The Swastika Textile Mills Ltd. Airlines Buildings 5th floor, 199, Churchgate Reclamation, Bombay 400 020	Sulphamethoxazole
9.	Shri V. G. Upadhya, 172, Sardargriha Building, 198, Lokmanya Tilak Marg, Bombay 400 002	(*i*) Propyphenazone (*ii*) Sulphamethoxazole

(*Source:* Director General of Technical Development, New Delhi)

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Indo-Soviet collaboration

- Drugs and Pharmaceuticals

At the fifth session of the inter-governmental Indo-Soviet joint Commission on Economic and Technical Co-operation, a protocol was signed on behalf of India by Mr. K. V. Ramanathan, Secretary, Ministry of Chemicals and Fertilizers and by Mr. Goryakovsky, Deputy Minister of Medical Industry, USSR for a long-term working programme of co-operation between the two countries in the field of drugs and pharmaceuticals. The working programme covers the period upto 1985 and includes setting up of production facilities for phytochemicals, insulin, aspirin, chloramphenicol and codeine phosphate from poppy husk.

The two sides have also agreed to exchange technological information regarding acetylacetone manufacture from diketene for the production of sulphadimidine. It has also been agreed to work jointly for the production of rifampicin and to exchange information on the production of vitamin B_6.

It has also been agreed to exchange information on technological processes for the manufacture of semi-synthetic antibiotics, synthetic drugs and vitamins. The items included are riboflavin, folic acid, 7-ADCA, cephalosporins, methacillin, cloxacillin, carbamicillin, allopurinol, sulphamethizole, chloropropamide and purine (xanthines). Possibilities of setting up of joint pharmaceutical facilities in South-East Asia, West Asia, Africa and Latin America will be explored and information in this connection will be exchanged on regular basis. Under the agreement, USSR will also give to India requisite technology for the production of a number of latest drugs like aninalone, acemin and nitroxoline. The Soviet Union indicated a number of drugs which they were importing at present and the Indian side agreed to provide them information about the Indian formulations which could be exported to them.

- Drug unit to be set up in H. P.

Soviet Union has agreed to help in setting up a drug and pharmaceutical plant in Himachal Pradesh. The proposed Rs. 2 crore project would be set up in public sector in collaboration with the Indian Drugs & Pharmaceuticals Ltd. and the Himachal Pradesh Government. Soviet Minister for Medicine and Industry, Mr. V. Goryakovsky, and Himachal Pradesh Chief Minister had a detailed discussion on this topic. Soviet Union has also agreed to co-operate in setting up a chain of medicinal herbs plantations in the state.

- Accord in medical fields

India and USSR have signed a plan of co-operation in the fields of medical sciences and public health for the period ending December 31, 1981. It was signed by Mr. Kirpa Narain, Secretary, Union Ministry of Health and Family Welfare and Dr. D. D. Venedsctoy, USSR Deputy Minister of Health. The plan envisages exchange of appropriate pharmaceuticals and biomaterials in the fields of communicable diseases, immunology and vaccine production, blood and blood products, ophthalmology, oncology and neurophysiology. It has been agreed to improve contacts in other fields of mutual interests through exchange of medical and technological information. Co-operation between scientific research institutes and mutual exchange of specialists etc. will also be taken up.

WHO to keep stocks of smallpox vaccine

The World Health Organisation offices in New Delhi and Geneva will keep in reserve freeze-dried smallpox vaccine, at an even temperature of −30°C, sufficient to vaccinate 200 million people.

The step is being taking at the recommendation of the Global Commission for the Eradication of Smallpox and for this a refrigerated depot is being constructed at the WHO office premises in New Delhi. The depot will also stock bifurcated needles. The stored vaccine would be tested periodically for potency.

South Korea leads in herbal export

Export market for medicinal plants is now being dominated by South Korea and China. India has, of late, registered a sharp decline in its export from Rs. 16.69 crore in 1978-79 to Rs. 12.84 crore in 1979-80. South Korea exported last year Rs. 75 crore worth of *ginseng* (a medicinal root) to USA. China has also entered the export market in a big way by exporting some of the plants which grow only in that country and are in much demand in USA and West Germany.

India's fall in herbal export can be attributed to attempts by some importers in France and USA to grow substitute plants in their own countries. The decline in demand has also affected the price of some harbs e.g., isabgul which was $ 2.5/kg two years ago is now selling at $ 1.8/kg. This has resulted in decline in production from 45000 tonnes in 1976-77 to 30,000 tonnes now. Isabgul is used in formulation of bulk laxatives.

Hungarian pharmaceutical industry to increase production

The Hungarian pharmaceutical industry which contributes 5 per cent of world's total exports of pharmaceuticals is now exploring new markets in Jamaica, Bangladesh and South-East Asia. The industry will also try to recapture the French market to which the export of Hungarian pharmaceuticals is static for the last many years.

Hungarian pharmaceuticals have been gaining reputation and are in demand throughout the world. Medimpex, the State Organisation responsible for the export of medicines, exported 200 million roubles and 125 million dollars worth of medicines in 1979 to over 90 countries. World's consumption of medicines is expected to grow by 10 to 12 per cent during eighties and to contribute its share the Hungarian pharmaceutical industry plans to increase its gross production three-fold in the current year.

News from Hungary, **19**(**5**), 9 (1980)

US pharmaceuticals export increases by 13.4%

Statistics published by US Department of Commerce's Bureau of the Census show that the export of pharmaceuticals increased to $ 1,591.2 million in 1979 from $ 1,405.5 million in 1978. The imports went down by 2%, from $ 449 6 million in 1978 to $ 440.6 million in 1979. The balance of trade was very favourable at 20.6%. Exports to Asian countries were as follows: Asian communist, $ 0.4 million ; Japan, 249.9; Near East Asia 66.8 ; Southern Asia, 17.2 and Rest of Asia, 95.2. The corresponding figures for imports from these countries were respectively as follows: $ 4.5 million, 61.3, 1.7, 1.1 and 2.9.

Scrip, No. **485,** 11 (3 May 80)

WHO plans a drug purchasing fund

Addressing the UNIDO's preparatory meeting in Cancum, Mexico, Dr. Hector R. Acuna, Director of Pan American Sanitary Bureau and WHO Regional Director, announced that the WHO proposed to establish a fund for the collective purchase in bulk of selected pharmaceuticals required for Primary Health Care (PHC) thereby substantially reducing their cost. The WHO would also promote the evaluation of drugs developed for specific parasitic, bacterial or viral diseases prevalent in tropics, through the supervision and co-ordination of large field trials sponsored by interested governments and the WHO, and financed by the manufacturers.

But Dr. Acuna regretted that the offer of pharmaceutical manufacturers to the WHO, in context of the action programme on essential drugs, has not been fully utilized. This may be because of certain restrictive conditions under which the products would have been made available and also the lack of commitment by the concerned governments towards proper distribution and use of the drugs and to the shortage of additional financial resources.

The fund proposal requires the identification of essential drugs used in the developing countries at PHC level and supply of information on their yearly requirements, unit prices and sources (local or imported). According to Dr. Acuna, the programme would initially select a few drugs of clinical and public health importance which are comparatively high priced and imported. The estimated requirements of the participating Less Developed Countries would be pooled so that tenders could be floated for the highest possible quantity. Bids from suppliers in a position to meet WHO quality standards would be considered. The products thus obtained would be made available to the participating countries at substantially reduced prices.

Scrip, No. **488,** 12 (14 May 1980)

Proposed drug pricing system in France faces criticism

Mr. Pierre Joly, President of French SNIP has highlighted the flaws in the proposed drug pricing reforms. According to him, the government had agreed politically to the industry's need to have remunerative prices so as to enable finance research and international expansion. But on examining the details of the proposed reforms the difficulties have come to surface. He cited the following points in support of his arguments:

(*a*) Although general price increases would be granted regularly with a free and permanent modulation, they would not solve the problem of those manufacturers with a low average weighted price. These manufacturers usually do not market enough products to take full advantage of the free modulation;

(*b*) The announced pricing freedom for new products was largely theoretical since manufacturers would not be granted reimbursement if their prices were considered too high. Every thing depended, therefore, on reimbursement criteria and their interpretation; and

(*c*) New copy or comparable products would not be approved for reimbursement if they were priced above corresponding, already marketed products. The industry is ready to accept this condition if the prices of marketed products were allowed to rise at par with inflation. Since in reality this may not happen, the reforms would result in a collapse of prices in real terms.

Scrip, No. **488,** 4 (14 May 80)

Company Reports

Albert David achieves record sales

Albert David Ltd., a Calcutta based company has increased its 1979 sales by 67% from Rs. 3.83 crore in 1978 to Rs. 6.38 crore in 1979. The net profit was Rs. 12. 3 lakhs in 1979 compared with a meagre Rs. 83,000 in 1978. The company also started production of metronidazole and oxyphenbutazone during 1979. Construction of a new factory for the manufacture of intravenous solutions has also been started.

Curewell sales slump

Curewell (India) Ltd., an Indo-Bulgarian joint venture, achieved sales of Rs. 71.5 lakhs for 1979 compared to Rs. 78.6 lakhs for 1978. The gross profit also came down by 29% from Rs. 16.1 lakhs to Rs. 11.4 lakhs for the periods under comparison.

Duphar-Interfran to expand

Duphar-Interfran has plans to expand its pharmaceutical and cosmetics manufacturing activities during the next five years at a cost of Rs. 5 crore. It has decided to build a new complex at Vapi (Gujarat) because there is no scope of expansion at the company's existing plant at Thane.

The expansion programme would include a number of new formulations and chemical products. The entire cost will be met through the company's internal accruals and if necessary by rights issue.

Glaxo to issue 36 lakh new equity shares

Glaxo Laboratories (India) Ltd. has proposed to issue 36 lakh new equity shares of Rs. 10 each as bonus shares in the ratio of one new bonus equity share for every equity shares held.

An interim dividend of 8 per cent on the equity shares for the current year has also been recommended. This dividend will be payable on the new bonus shares also. An interim dividend of 9 per cent was paid for the year ending June '79.

Munirabad Drug Company to make ephedrin-hydrochloride

Munirabad Drug Company (Pvt.) Ltd. has set up a plant to manufacture ephedrin hydrochloride. The annual capacity of the plant is 15 tonnes and the process know-how has been supplied by its sister concern Munirabad Chemical Company.

Sandoz sales up but profits go down

Sandoz (India) Ltd. has achieved a sales of Rs. 48. 6 crore in 1979, a 9.5% increase from 1978 sales of Rs. 46.3 crore. Gross profits however, declined from Rs. 6.78 crore in 1978 to Rs. 5.83 crore in 1979. Net profit was Rs. 1.43 crore compared to Rs. 1.52 crore for 1975. A dividend of 16% has been proposed.

Wyeth companies in India to merge

Wyeth Laboratories Ltd., Wyeth (India) Pvt. Ltd. and John Wyeth & Brother Ltd., the three Wyeth companies operating in India, are amalgamating into a single company to be known as "John Wyeth India Pvt. Ltd". The merger is a result of a "package" offer by the Government in pursuance of the requirements of the Foreign Exchange Regulation Act. The new company hopes to be allowed to retain a 74% foreign equity as most of the products of Wyeth Labs have been classified as high technology drugs. The company plans to invest Rs. 6 crores in an expansion programme covering 16 new high technology bulk drugs including norgestrel and dexamethasone.

Squibb to establish joint-venture in China

President of the Squibb International, Mr. Michael W. Percopo, has signed in Beijing a joint venture with the China National Company of the Pharmaceutical Industry. This is the first Sino-US venture in the field of pharmaceuticals. In this venture each party will contribute 50% of the capital and will hold 50% of the equity. The Chairman of the new joint-venture will be from Chinese side while Squibb will assume operational management.

The venture will manufacture and finish a significant range of Squibb's products in China, some of which will be exported to ensure that the venture is self-sufficient in foreign exchange.

Scrip, No. **488,** 6 (14 May 80)

Medec Prize for Duxil

Duxil, a combination drug by Servier has been awarded French Medec Prize for its original contribution to therapeutics. It is a combination of almitrine—a new chemical synthesized by Servier—and raubasine and is claimed to increase the oxygen content of blood in arteries and is indicated for the treatment of cerebral vascular conditions.

Scrip, No. **492/493,** 4 (31 May 80)

Research and Development

BCG to be re-evaluated

BCG will be subjected to a second study in India to re-evaluate its efficacy in immunisation against tuberculosis. The Indian Council for Medical Research (ICMR), WHO and US Centre for Disease Control are co-sponsoring this study. This project will be conducted in the Srinagar region. The first trial by ICMR was carried out in the Chingleput district of Tamil Nadu which had led to a startling conclusion that BCG immunisation offers no protection against tuberculosis under certain conditions.

BCG vaccination supported

Dr. Y. C Mathur, a paediatrician working in the Niloufer Hospital, Hyderabad has advocated the necessity of immunizing children with BCG vaccination even though an ICMR and WHO sponsored study has indicated that it affords no protection against the bacillary form of pulmonary tuberculosis during the first 30 months after vaccination. Besides, it had no effect, either beneficial or harmful, in people already infected at the time of vaccination.

According to Dr. Mathur many studies have shown that children who had been given the BCG vaccination developed more resistance to tuberculosis than those not vaccinated. Efficacy depends upon a number of factors including the strain of BCG used, the dosage, the degree of endemicity and the degree of sensitization of the population. A trial at Madanapalli in Andhra Pradesh has indicated 60% efficacy after 7 1/2 years while a similar trial among North American Indians showed a protective efficacy of about 80%. Dr. Mathur emphasised the need to continue BCG vaccination of children since in India a high risk of infection persists. According to him indepth study of the BCG vaccination is required before any thought to its discontinuation is given a shape.

Viral vaccines found safe by a US panel

A panel of US medical experts in its report to FDA has confirmed the safety and effectiveness of the major viral vaccines on the American market. These vaccines are for polio, measles, small pox, rubella, mumps, rabies, yellow fever and influenza. Since these play a major role in reducing illness and deaths associated with viral diseases their continued and vigorous use in childhood immunisation programmes has been advocated.

Scrip, No. **484,** 10 (30 April 1980)

Birth control vaccine in 10 years

A team of researchers working at the Wellcome Laboratories of the Institute of Zoology, London, has achieved success in controlling the fertility of marmoset monkeys and rabbits by immunizing them with a vaccine. The vaccine aims to block the proteins that are essential components of both male and female reproductive control mechanisms. It is expected to prevent not only ovulation in human females but also the development of sperms in males, so that birth control can be exercised through both the sexes.

Antidote for paracetamol overdose

A team of doctors working at Royal Infirmary, Edinburgh, UK has found an effective antidote to paracetamol overdosage. Paracetamol, a very safe and efficient pain killer can kill a person within five days if between 15 to 20 tablets are taken in a single dose. The antidote N-acetylcysteine must be injected *iv* into the victim within 8 hours of an overdose. Paracetamol changes during a chemical reaction in the liver into a dangerous metabolite which eventually damages the liver fully. N-acetylcysteine traps this chemical and converts it into a completely harmless substance.

Studies underway on optimum drug dosage for asthma

Drs. B. Emmerson and Jerma Ahokas of the Department of Medicine, University of Queensland, have initiated a two-year study on the most common asthma drug theophylline with the aim of finding out its optimum dose for individual sufferers. The drug after entering the bloodstream dilates the bronchial passage, thus allowing asthma sufferers to breathe. Too high a concentration causes toxic effects such as headache and nausea.

According to the researchers, the drug is metabolised in the liver and if the enzymes were stimulated the drug is handled too quickly by the body to have a therapeutic effect. If the enzymes were inhibited the drug stayed in the body and possibly built up to toxic levels. The drug concentration in the blood is affected by smoking, other counter-acting drugs, age, environment and dietary factors.

A new drug for diabetes

A novel way of treating diabetes has been developed by the Research Development Corporation of Japan in which the diabetic patient generates his own insulin instead of getting it from external source. The drug called Islet Activating Protein activates the insulin generating function of the pancreas.

The new drug has, so far, proved free from all dangerous side effects and works only when there is demand for insulin secretions. A single dose of the drug will be sufficient for as long as one month.

Interferon to be tested in cancer patients

The US National Cancer Institute has asked Warner Lambert Ltd. to supply 50 billion units of interferon, costing about $895,000, within two years for testing on 150 cancer patients. The interferon will be produced at the Warner Lambert/Parke Davis research laboratories in Michigan, USA from white blood cells and other proteins centrifuged out of human blood.

Meanwhile, Abbott Laboratories have also announced plans to increase production of interferon from a superior tissue culture method which will involve protein extracted from human fibroblast cells.

Blood vessels' growth regulator identified

A substance that helps in the growth of blood vessels, and thus aids cancerous growths, has been identified by a team of Australian biologists led by Dr. Brian Mcausalan of the Molecular and Cellular Biology Unit of Australian Commonwealth Scientific and Industrial Research Organisation. The substance called angiogenic factor, has been identified as an ionic or non-metallic copper. It has been known that tumours release some factors, which induce new blood vessels to grow, consequentially increasing the tumour size also. But until now, no one had been successful in isolating this factor. The present discovery has a far reaching application, for example, means could be found out to suppress the effect of ionic copper to temporarily stop the growth of tumours.

The discovery however, has given rise to serious doubts about copper intrauterine devices.

Interferon effective in nasopharyngeal cancer

Success was achieved in treating a case of large tumour in epipharynx, diagnosed as an undifferentiated malignant lymphoepithelioma, with interferon. The tumour and cervical lymph nodes were irradiated and the patient, an 11 years old boy, was placed on chemotherapy for 4 months. Six months after chemotherapy was stopped, a retrobulbar tumour had developed necessitating radiation and chemotherapy again. Two years later, the boy still on chemotherapy experienced another relapse this time affecting his brain. Dexamethasone treatment was given for 46 weeks resulting in only temporary improvement. At this time, pharmacotherapy with human fibroblast interferon was started, 4 × 10^6 units daily for 5 weeks by 30 minutes *iv* infusions The boy steadily improved after 3-4 weeks of interferon therapy. A CAT scan showed regression of tumour at all sites and a normal ventricular system. It is suggested that nasopharyngeal cancer may be virus-induced, in view of the great success achieved here with the antiviral agent, interferon. An *in vitro* culture of this tumour showed interferon to inhibit and kill all cancer cell lines, indicating a direct action on tumour cells rather than an effect on immune response.

Inpharma, No. **236,** 12 (10 May 80)

Combination drugs: Pros and Cons

More than a third of new drug products introduced all over the world in 1978 were fixed-ratio combinations. But the WHO's list of 240 'essential' drugs contains only 7 combination drugs.

Among combination drugs, the fixed ratio combination products have certain advantages as in case of sulfamethoxazole-trimethoprin (co-trimoxazole) where two successive steps in bacterial folate metabolism are blocked. In some cases there may be improved efficacy from a combination product. In the hormonal control of ovulation with an estrogen and a progestogen, flexibility in dose is not required and combination products are acceptable. In certain combination drug products side effects of one component may be reduced by another (propranolol + hydralazine, levodopa + decarboxylase inhibitor; isoniazid + pyridoxine). Combination products also offer greater convenience to the patient, improve compliance rates and often cost less than the individial component drugs.

However, there are many disadvantages of combination drugs, such as, (*i*) there can be no separate dosage adjustment of the component drugs though for many drugs the effective dose drug half-life and therapeutic range of plasma drug concentration varies among patients. Fixed ratio combination drugs rarely suit these conditions, (*ii*) it is difficult to pinpoint the cause of allergy or adverse effect to one of the component of a drug combination, (*iii*) some drug combinations are irrational (anti-inflammatory steroid + sedative; barbiturate + analgesic), ineffective (analgesic mixtures), or undesirable (laxative + analgesics, corticosteroid + non-steroid antirheumatic agent) and (*iv*) brand names of combinations often fail to disclose their ingredients.

Some regulatory bodies have already initiated action on drug combinations. Committee on Review of Medicines in UK has advised withdrawl of licences for combination products containing a barbiturate on grounds of its hazard or inadequate evidence of efficacy. In USA out of some 1200 drug combinations marketed between 1938 and 1962 and reviewed independently for the Food and Drug Administration in the 1960's, only 45 were considered effective.

Inpharma, No. **237,** 2 (17 May 80)

Gossypol as a topical spermicide

In 99.9% of the 4000 Chinese men, Gossypol—a cotton plant pigment—produced complete infertility. The subjects were treated systemically for more than 6 months. However as the mode of gossypol's action is not known a study was recently performed to define it. Human sperm cells were rapidly, but not immediately, immobilized by gossypol (25-100 μ mol/L). Gossypol could be useful as a spermicidal agent when applied either directly to vaginal mucosa or taken systemically by men.

Inpharma, No. **235,** 13 (3 May 80)

Tromaril, a new non-steroidal anti-inflammatory agent

Tromaril (RH-8, Unichem Lab, Bombay), a new non-steroidal anti-inflammatory agent has been found to produce diuresis and natriuresis in mice. Six healthy male volunteers were subjected to usual tests with this drug and it was found that natriuretic property of tromaril had an advantage over other drugs of such category particularly when used in patients with salt and water retention problem. However, the effect of chronic treatment with tromaril on sodium excretion needs to be assessed before advocating it for long term use in such patients.

Inpharma, No. **238,** 13 (24 May 80)

REGULATORY NEWS

Guidelines for canalised drugs during 1980-81

The guidelines announced by the Government for the allocation of canalised drug items for 1980-81 have adopted a liberal policy towards small scale sector by allowing it a growth rate of upto 50 per cent in the allocation of items over the itemwise entitlement in the previous year.

The policy for the new small scale units will remain same as that during 1979-80 and the new units will be entitled to the release of canalised drug items of a value not exceeding Rs. 3 lakhs. Among the existing units, the units with a sales turnover of not more than Rs. 1 crore may be allowed a growth factor of 50 per cent; those exceeding Rs. 1 crore may be allowed a plus growth rate of 30 per cent subject to a minimum applicable to new units. Small scale units which had not given any growth rate under 1979-80 policy because they had received excess allocation the previous year, the notional entitlement for 1979-80 would be on the basis of allocation in the current year.

However, the unit will be free to ask for additional quantities of any item it received last year or any other item by surrendering 15 per cent entitlement of any or each item. But the additional quantity asked for must not exceed 30 per cent of the unit's entitlement of the item for current year.

In backward areas, for the units set up by specified categories of persons—including scheduled castes and scheduled tribes—the maximum value entitlement will be Rs. 5 lakhs. Moreover, for such units the earnest money will be just one per cent, instead of usual 2 per cent. They will also be allowed to register their requirements for 15 months instead of the normal 12 month period and may be given priority at the time of allocation of goods.

Units registered with the Directorate General of Technical Development (DGTD) will get canalised drug items either on the basis of formulation capacities indicated in their licences or the higher allocation received by them during the three years ending March 77. Among these units those having a registered export value of not less than 10 per cent of the ex-factory value of their actual production in the last two years, will get an additional 10 per cent allocation of their itemwise entitlement. Where the export value of such units in 1979-80 is at least 50 per cent of the production, the additional allocation will be 50 per cent of their entitlement.

Loan licensee units will receive canalised raw materials of the value not more than Rs. 1 lakh in the first year which will go up to Rs. 2 lakh on completion of two years. Units completing three years are expected to have set up their own manufacturing premises. They will be allowed a growth rate on par with small scale units after they have given proof that they have actually established their own units.

In the case of items decanalised for imports, already registered demand with the concerned canalised agency will not be allowed to be cancelled except with the consent of that agency. It has also been decided that State Chemicals and Pharmaceuticals Corporation will be free not to release other canalised drug items unless the units lift decanalised items simultaneously.

The guidelines state that to ensure that only genuine small scale units avail themselves of these facilities, a certificate regarding the total value of their plant and machinery, which should not exceed Rs. 10 lakhs, will have to be produced.

Import of three more drug intermediates canalised

Import of three more drug intermediates has been canalised through State Chemicals and Pharmaceuticals Corporation of India. They are *p*-nitro chlorobenzene, *o*-nitrochlorobenzene and *m*-dinitrobenzene. These drugs were in the restrictive list of the recently announced import policy. By another amendment to the import policy, diosgenin, a drug intermediate, has been put in restricted list from OGL. These steps have been taken to regulate import of these items with respect to indigenous production and demand.

Several antihistamines to be evaluated for toxicity

According to a paper presented by the US FDA's New Drug Evaluation Division at a tripartite meeting of the US, UK and Canadian Health authorities held in October 1979, methapyrilene—an ethylene diamine—induces hepatocarcinogenicity in animals. Products containing methapyrilene were withdrawn from several markets last year because of this carcinogenicity finding. Based on structural similarity to methapyrilene, eight compounds have been identified for evaluation. They are: diphenhydramine, promethazine, tripelenamine, doxylamine, thenyldiamine, antazoline, methdilazine and chloromethapyrilene.

Scrip, No. **485,** 9 (3 May 80

More drug intermediates for small-scale industry

The Standing Committee set-up for reviewing the list of items reserved for small sector has recommended the inclusion of following six items in the reserve list: (1) Stearate of aluminium, (2) Stearate of magnesium, (3) Stearate of Calcium, (4) Stearate of zinc, (5) Methyl salicylate (based on purchased salicylic acid), and (6) Halogenated hydroxyquinolines (starting from 8-hydroxyquinoline) except for integrated schemes for the manufacture of 8-hydroxyquinoline.

The committee was headed by Mr. Lavraj Kumar, Chairman, Bureau of Industrial Costs and Prices.

Multivitamin reformulation time limit extended

The time limit laid down by the Drugs Controller of India for manufacturers to reformulate multivitamin products in line with the revised limits was extended for the fifth time to June 30th, 1980, from March 31st, 1980. This was done so as to give the Ministry of Petroleum and Chemicals more time to grant price approvals in respect of reformulated products.

More foreign drug companies dilute equity

Three of the seven foreign drug companies engaged in formulation activity only, have diluted their foreign holdings to 40 per cent as required under the new drug policy. These companies are Anglo-French (80% foreign equity), Indian Schering (88.6) and Nicholas of India (87.3%).

Anglo-French was, so far, making only non-essential drug formulations but now it plans to go in for the manufacture of important bulk drugs also. The other two companies have merged into a single unit under the name of Nicholas Laboratories of India.

The remaining four companies which still now have not diluted their equity to 40 per cent are Abbott Laboratories (100% foreign equity), Carter Wallace (49.46%), C.E.Fulford (100%) and Smith Kline & French (a branch). Abbott has already submitted its dilution plans and also its proposal to take up the production of six bulk drugs. The company was making so for only categories II and III drugs. Similarly C. E. Fulford, Carter Wallace and Smith Kline & French have submitted their plans for dilution of foreign equity and are awaiting Government's decision.

Japanese drug re-evaluation

The Japanese authorities have decided to re-evaluate new drugs four or six years after their introduction into the market, depending upon their novelty, according to a note published by the Japanese Ministry of Health and Welfare. Under the revised Pharmaceutical Affairs Law the drugs to be re-evaluated after six years are:

(1) Those with novel active ingredient;

(2) Combination products exclusively used in hospitals with constituents or combination ratios different from those given already in approved Japanese Pharmacopoeia; and

(3) Combinations which though similar to already marketed drugs have different routes of administration.

Drugs which will be re-evaluated after four years are:

(1) drugs whose active ingredient and routes of administration are similar to already marketed compounds but whose indications and efficacy are different; and

(2) known drugs with distinctly different direction and doses.

The re-evaluation will cover: (*a*) the incidence and nature of adverse reaction particularly over long term use and in particular patient groups such as children and the elderly; (*b*) the effectiveness of the product and any new effectiveness claims; (*c*) any interactions with co-prescribed agents; and (*d*) and published or unpublished reports relating to safety and efficacy of the drugs in question.

Scrip, No. **488,** 11 (14 May 80)

Japan enacts new laws for drug control

The regulatory agency of Japan, the Pharmaceutical Affairs Bureau of the Ministry of Health and Welfare, has enacted some broad-based legislation to control drugs, quasi-drugs, cosmetics and medical devices under the regulation of a single agency. The new law requires pre-marketing clearance of all drugs, quasi-drugs, cosmetics and medical devices those imported as well as those manufactured in Japan.

The amendments to the Pharmaceutical Affairs Laws were carried out in September 1979 but will be enforced only from 30 September, 1980. Of course, a few provisions of the amendments relating to the manufacture or import approval of new drugs (excluding Japanese Pharmacopoeial products), re-examination of new drugs, their review, report on adverse drug reactions, emergency order, cancellation of approval and approval fees have already been enforced from 1st April, 1980.

Japan Medical Gazette, **17,** 1 (20 April 80)

Japanese adverse drug reaction relief fund becomes operative

From May 1st 1980, the Japanese relief fund for the victims of adverse drug reactions has started making payments. According to an ordinance the fund will pay for (1) medical expenses; (2) medical care allowances; (3) pensions/allowances for the disabled adults/children; (4) pensions for victims, survivors; (5) a one-time allowance for surviving victims; and (6) funeral and related expenses. Claims are to be submitted within two years, or they lapse, and also those receiving disability pensions/allowances can be required to be re-examined.

Scrip, No. **488,** 11 (14 May 80)

Venezuela adopts WHO and FDA cosmetics standards

Health and Social Services Ministry of Venezuela has adopted new regulations for cosmetics conforming to standards of "Good Practices in Manufacturing and Quality Control of Drugs" as established by the World Health Organization. The regulations for carcinogenicity labelling and testing of hair dyes as established by the US Food and Drug Administration, have been adopted. All these regulations will be enforced by the Division of Drugs and Cosmetics of the Venezuelan Department of Public Health.

International Drug Regulatory Monitor,
No. **84,** 7 (May 80)

FDA for establishing bioequivalence of psychotropics

A task force of US Food and Drug Administration has recommended that bioavailability and bioequivalence of both old and new psychotropic drug products should be established to assure bioequivalence of all marketed products i.e. the products should contain identical amounts of the same active ingredient in the same form. This is necessary if the products are intended to be used interchangeably for the same therapeutic effect.

Following 27 classes of drug products have been listed for establishing bioequivalence requirements:

1. Anticonvulsants
2. Tricyclics
3. Xanthines
4. Procainamide
5. Corticosteroids
6. Sulfonamides
7. Thiazides
8. Quinidine
9. Carbonic anhydrase inhibitor
10. Chlordiazepoxide
11. Probenecid
12. Propylthiouracil
13. Phenothiazines
14. PAS
15. Coagulants
16. Androgens
17. Methenamine
18. Cardiac glycosides
19. Thyroid
20. Nitrofurantoin
21. Antineoplastics
22. Sulfones
23. Anticoagulants
24. Isoprotesenol
25. Pyrimethamine
26. Vitamin D
27. Reserpine

International Drug Regulatory Monitor, No. **83,** 8 (April 80)

KARNATAKA STATE DRUGS CONTROL DEPARTMENT

(*Monthly Report:* March 1980)

The department granted/renewed 6 manufacturing and 1470 licences of sales establishments during this month. A total of 337 inspections, including hospital inspections, were carried out. Three fresh cases under the Drugs and Cosmetics Act, 1940 and 4 cases under the Drugs (Prices Control) Order, 1979 were launched during this month.

Four licences of manufacturing establishments and 30 licences of sales establishments, were cancelled; 30 licences of sales establishments were invalidated. 13 licensees of sales and manufacturing establishment were warned.

INDUSTRIAL LICENCES

ISSUED DURING MARCH 1980

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type and No of Licence
			Basic Substances:		
1.	Anglo-French Drug Co. (Eastern) Ltd. 28, Tardeo Road, Bombay	Maharashtra	(*i*) Chlordiazepoxide	800 kg	New Article CIL : 77/80 dated : 21.3.80
			(*ii*) Diazepam	500 ,,	
			(*iii*) Nitrazepam	500 ,,	
			(*iv*) Norgestrel	10 ,,	
			(*v*) Ethinyl estradiol	20 ,,	
			Formulations:		
			(*i*) Sedovit 10 mg tablet (chlordizepoxide)	25 million	
			(*ii*) Flavit 5 mg tablet (diazepam)	25 million	
			Flavit 15 mg/2ml ampoule (diazepam)	5 kilo ltrs	
			Flavit 2 mg/5 ml syrup (diazepam)	50 kilo ltrs	
			(*iii*) Nitravit 5 mg tablet (nitrazepam)	25 million	
			Nitravit 5 mg/ml drops (nitrazepam)	5 kilo ltrs	

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type and No. of Licence
			(*iv*) Novestryl tablet (ethinyl estradiol 0.05 mg plus norgestrol 0.5 mg per tablet (*v*) Oestryl tablet (ethinyl estradiol 0.05 mg per tablet)	14 million 16 million	
2.	Bakul Aromatic & Chemicals (P) Ltd., Sterling Centre, 4th floor, 19/2, Dr. Annie Besant Road, Worli, Bombay 400 018	Maharashtra	(*i*) Theophylline and aminophylline (*ii*) Synthetic caffeine (*iii*) Acetic acid (by product)	114 tonnes 66 ,, 200 ,,	New Unit CIL : 72/80 dated : 18.3.80
3.	Cadila Laboratories (Division of Cadila Laboratories Pvt. Ltd.) Maninagar, Ahmedabad	Ahmedabad	Ethambutol HCl	15 tonne	New Article CIL : 64/80 dated : 6 3.80
			Mebendazole (bulk drug)	10 ,,	CIL : 65/80 dated : 7.3.80
			Tinidazole (bulk drug)	20 ,,	CIL : 73/80 dated : 7.3.80
4.	Hindustan Antibiotics Ltd., Pimpri, Pune-18	Maharashtra	Gentamycin sulphate	1000 ,,	New Article CIL : 63/80 dated : 6.3.80
5.	I. D. L. Chemicals Ltd., P. B. No. 397,	Karnataka	(*i*) Astrafer (iron sorbitol complex)	1500 kg	New Unit CIL : 71/80

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type and No. of Licence
	Malleswaram, Bangalore		(*ii*) Isosorbida dinitrate (ISDN)	500 kg	dated : 18.3.80
			(*iii*) Terbutaline sulphate	100 ,,	
			(*iv*) Prilocaine HCl	3000 ,,	
			(*v*) Lunelax substance (psyllium husks)	250 tonnes	
			(*vi*) Xylocaine	5000 kg	
6.	Indian Drugs & Pharmaceuticals Ltd., Kookatapally, Hyderabad-37	Andhra Pradesh	(*i*) Diazepam tablet	25 million (existing) 85 ,, (after expn.)	Substantial Expansion IL : 14/80 dated : 21.3.80
			(*ii*) Metronidazole tablet	25 ,, (existing) 100 ,, (after expn.)	
			(*iii*) Chewable vitamin C Vitamin C tablet	50 ,, (existing) 200 ,, (after expn.)	
7.	Indian Drugs & Pharmaceuticals Ltd., N-12, South Extension-1, New Delhi 110 049	Delhi	Methyl dopa tablet	50 million (after expn.)	Substantial Expansion IL : 16/80 dated: 22.3.80
			Under this New Unit licence has been granted to various formulations (Syrups, tablets, capsules injections etc.) of antibiotics, antacids, antineurotics, enzymes,		New Unit CIL : 88/80 dated : 27.3.80

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type and No. of Licence
			laxatives, analgesics, diuretics, B-complex, tranquillizers, anti-asthamatics, antihistaminics, haematinics, antibacterials, anti-inflammatory, ophthalmic ointments etc.		
8.	Orient Pharma Pvt Ltd., Old Trunk Road, Pallavaram, Madras 600 043	Tamil Nadu	Valethamate bromide (bulk drug)	300 kg	New Article CIL : 60/80 dated : 3.3.80
9.	Sunil Synchem Ltd., 909, Ansal Bhavan, 16, Kasturba Gandhi Marg, New Delhi 110 001	Delhi	L-methyl dopa	24 tonnes	New Unit CIL : 58/80 dated : 3.3.80
10.	Urvi Investment Ltd., Morarjee Mills Compound, Dr. Ambedkar Road, Parel, Bombay 400 012	Maharashtra	Chloroquine diphosphate	45 tonnes	New Article IL : 53/80 dated : 13.3.80
11.	Woolcombers of India Ltd., 31, Netaji Subhas Road, Calcutta 700 001	West Bengal	(*i*) Anhydrous lanolin (*ii*) Lanolin (commercial grade)	76 tonnes 46 tonnes	C.O.B. IL : 12/80 dated : 12.3.80

NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
1.	*Analgesic*			
	Diflunisal	Dolobid	Merck Sharp & Dohme	Australia
2.	*Antiallergy*			
	Ketotifen	Zaditen	Warda Pharma	France
3.	*Antianxiety*			
	Ketazolam	Anxon	Beecham	UK
4.	*Antiarrhythmic*			
	Disopyramide	Norpace	Searle	Indonesia
5.	*Antibacterial*			
	Amoxicillin	Tigamox	Squibb	Indonesia
	Erythromycin base	Superthrocin	Prafa	Indonesia
	Sulphametrole + trimethoprim	Lidaprim	Nicholas	Indonesia
	Tetroxoprim + sulphadiazine	Tibirox	Roche	W. Germany
	Trimethoprim	Syraprim	Wellcome	UK
	Trimethoprim + sulfamethoxazole	Co-trizol	Parke Davis	New Zealand
6.	*Antidepressant*			
	Lofepramine	Tymelyt	Leo	Sweden
7.	*Antidiarrhoeal*			
	Loperamide	Normotil	Pharos	Indonesia
8.	*Antifungal*			
	Tinidazole + nystatin	Fasigyn-nystatin	Pfizer	Indonesia

Contd.

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
9.	*Antihistamine/corticosteroid*			
	Triamcinolone + carbinoxamine maleate	Kenantist	Squibb	Indonesia
10.	*Antihypercholesterolemic*			
	Probucol	Lurselle	Lepetit	UK
11.	*Anti-inflammatory*			
	Benoxaprofen	Opren	Dista	UK
	Piroxicam	Felden	Mack/Pfizer	W. Germany
	Proquazone	Biarison	Sandoz	S. Korea
12.	*Antiviral*			
	Interferon + IGA 11S	Inter-A11	Sidus	Argentina
13.	*β-Blocker*			
	Carazolol	Conducton	Klinge	W. Germany
14.	*β-Blocker/diuretic*			
	Propranolol + bendrofluazide	Inderetic	ICI	UK
15.	*Bronchodilator*			
	Ipratropium bromide	Atrovent	Boehringer Ingelheim	New Zealand
	Theophylline	Neulin SA	Riker	UK
16.	*Calcium regulator*			
	Calcitriol	Rocaltrol	Roche	UK
17.	*Decongestant*			
	Oxymetazoline HCl	Afrazine	Kirby-Warrick	UK
18.	*Estrogen*			
	Epimestrol	Stimovul	Organon	Indonesia
19.	*Nootropic*			
	Arginine pidolate	Adiuvant	Manetti & Roberts	Italy

Sl. No.	*Generic Name*	*Trade Name*	*Manufacturer*	*Country*
20.	*Oral contraceptive*			
	Lynestrenol + ethinylestradiol	Restovar 28 Micro	Organon	Indonesia
21.	*Topical corticosteroid/antimicrobial*			
	Hydrocortisone-17 butyrate + chlorquinaldol	Locoid C	Brocades	UK
22.	*Vasodilator*			
	Buflomedil	Loftyl	Abbott	Indonesia

MEETINGS/SEMINARS

8th Asian Congress of Pharmaceutical Sciences

Under the auspices of Federation of Asian Pharmaceutical Associations, the 8th Asian Congress of Pharmaceutical Sciences will be held at Kyoto (Japan) from August 25th to 28th, 1980. The theme of the congress is "Better health care and pharmacists responsibility". The major scientific activities of the congress will be: (a) General assembly, (b) Symposium and (c) Scientific sessions.

An exhibition devoted to pharmaceutical industry will also be held simultaneously.

Indian Pharmaceutical Association

Dr. A. K. Kapadia has been elected President of the Indian Pharmaceutical Association for the period April 1980 to March 1982. Dr. Ajit Shirodkar and Dr. J. B. Dave have been elected as Vice-President and Secretary respectively. Shri J. B. Asrani and Shri S. N. Desai are joint-secretary and treasurer respectively.

Mexico Conference: Price disparities discussed

Variation of drug prices between different countries was the main topic of discussion at UNIDO preparatory meeting held during April 24-27 in Cancun, Mexico. The main meeting—the first of its kind—on the pharmaceutical industry will be held in December 1980 in Lisbon. The preparatory meeting was attended by 97 experts, including 43 official delegates from 29 countries.

The debate in Cancun centred around two data tables which were a part of a briefing paper "Quick investigation of the key elements hampering the development of the pharmaceutical industry in developing countries," prepared by the UNIDO Secretariat. According to these tables, price variations as much as 2800% exist in the international market. For example, the import price of one thousand 250 mg tablet of ethionamide in Algeria was US $5.0 in 1976, compared to US $144.0 in Switzerland. Most disparities were not of this magnitude, however, and price difference of three to four times was common. Further, the tables showed an import price of bulk tetracycline at US $30.2 in Bangladesh and a high $240.0 in Iran; streptomycin at $18.0 in Brazil and $86.3 in Peru at 1978 price levels. These data were obtained by sending consultants to selected countries in Africa, Asia and Latin America during 1979. Various constraints on the growth and development of the pharmaceutical industry in these countries were identified. These include the wide disparity in prices at which formulations, bulk drugs and intermediates were supplied to different countries and the unfavourable terms and conditions for the transfer of technology.

The essential drugs identified for discussion at the meet were: acetylsalicylic acid, ampicillin, bephenium, blood fractions, chloroquin phosphate, dapsone, diethylcarbamazine, ethambutol, ethinylestradiol, erythromycin, furosemide, isoniazid, methyldopa, paracetamol, benzyl penicillin, piperazine, primaquine, reserpine, streptomycin, sulphadimidine, tetracycline, tolbutamide, vitamin A, B_{12} and C.

The meeting also agreed on the following agenda for December 1st-5th First Consultation meeting at Lisbon:

(1) The UNIDO secretariat should identify sources of bulk drugs and intermediates for the 25 essential drugs;

(2) (*a*) UNIDO should work together with UNCTAD and WHO in drafting a code of trade distribution and transfer and development of pharmaceutical technology, as recommended at the Havana Conference of Non-aligned Countries. Any results achieved before December 1980 should be presented to the First Consultation.

(*b*) A detailed draft of a model contract for the transfer of technology should be prepared for the First Consulation and be circulated well in advance (Participants from developing countries wanted UNIDO to have a "neutral approach" towards the treatment of this subject); and,

(3) (*a*) A directory should be produced listing possible sources of the most up-to-date and reliable technology for the production of essential drugs. It should also indicate the terms and conditions for the transfer of such technology;

(*b*) UNIDO after consulting relevant developing countries and regional organisations should prepare an action programme that would propose which active ingredient can be produced in which region and also how and when.

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BOOK REVIEWS

The eradication of smallpox from India, By R. N. Basu, Z. Jezek & N. A. Ward, World Health Organisation, South-East Asia Regional Office, New Delhi, 1979, Pages 346, Price: Sw. fr. 30.

Written by a health official of the Government of India and two WHO staff members who were actively involved in the Indian National Smallpox Eradication Programme, it sets forth in detail what was done at each stage of the programme, the national strengths which facilitated the programme as well as the weaknesses which hampered progress. Examples of the many forms used are given throughout the volume.

The Indian National Smallpox Eradication Programme was first launched in 1962 as the number of smallpox cases in India represented over one-half of the total reported from throughout the world. The policy of mass vaccination achieved a reduction in smallpox incidence in the southern states but was less successful elsewhere. In 1973, a new strategy of intensified search and containment was put into effect. In January 1975, operation smallpox "Target Zero" was launched and field operations were further intensified. Instead of village-to-village searches, house-to-house searches were introduced. On 17 May 1975, the last known indigenous smallpox case occurred.

The absence of smallpox was confirmed by a national independent assessment committee, which visited 11 States, and later on by an international commission of eminent national and international scientists which met in 1977. Their reports stated that no evidence had been found of any smallpox cases having occurred after May 1975.

The work provides fully documented guidance to methods for the control or evaluation of a communicable disease. It is thus of considerable interest to public health workers, epidemiologists and those concerned with the training of health personnel. An annex lists more than 1000 participating officials from India and from 30 other countries. A bibliography is provided containing some 300 references to published and unpublished work on the subject.

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Approaches to planning and design of health care facilities in developing areas. Volume 3, Edited by B. M. Kleczkowski & R. Pibouleau, World Health Organization, Geneva, 1979 (*WHO Offset Publication* No. 45: ISBN 92 4 170045 9). Pages 149, Price: Sw. fr. 18.

This volume is the third in a series issued by the World Health Organization and is intended for all concerned in planning, programming, building, staffing and operating health care facilities in developing countries where one often follows the approaches adopted in developed countries without proper consideration of the real needs of populations and the most efficient and economical ways of meeting those needs.

All the three volumes contain a wide-ranging selection of articles so that every member of a planning team learn of the other members' problems while being in touch with advances and new ideas in his own field.

Volume 3 contains six articles. The design and operation of inpatient areas are described in an article by R. Llewelyn-Davies & J. Weeks, while outpatient departments and ambulatory services are dealt with by L. C. Vogel. J. Cook writes of the minimum requirement for surgery, P. E. S. Palmer of radiology in basic-care hospitals and clinics, and J. Cooper-Poole of equipment for hospitals and other health care facilities in developing countries. The sixth article in this volume, by M. Torfs, is on the use of mobile and transportable health facilities in developing countries. The volume also contains a synoptic table of topics to be covered in the series as a whole.

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Manual for rapid laboratory viral diagnosis, By J. D. Almeida et al, World Health Organization, Geneva 1979 (*WHO Offset Publication* No. 47). ISBN 92 4 1700475. Pages 48, Price: Sw. fr. 6.

Rapid laboratory diagnosis plays an essential role in the management of virus diseases. The diagnostic techniques described in the present manual may be taught to students in all countries, even where the sophisticated tissue culture methods for virus isolation are not practicable. It is hoped that the manual will encourage the use of techniques for investigating virus diseases, such as rabies, viral hepatitis, and rotavirus infections which particularly affect developing countries.

The four main categories of rapid viral diagnostic technique are: electron microscopy, immunofluorescence, enzyme techniques, and radioimmunoassay. Electron microscopy is not practicable in many developing countries, but some of them have centres with the necessary equipment. This manual therefore includes a section on electron microscopy to encourage its use wherever possible. Only the indirect technique of immunofluorescence has been considered, except for rabies. Among the enzyme techniques described are the enzyme-linked immunosorbent assay (ELISA) for antigen and antibody detection, and the immunoperoxidase method (non-solid phase) for diagnosing rabies. Emphasis is laid also ōn the detection of rotaviruses by ELISA, of respiratory virus by immunofluorescence, and of hepatits A virus IgM antibody by radioimmunoassay (hepatitis B was dealt with in a previous publication issued by the Center for Disease Control, Atlanta, United States of America, in association with WHO). Radioimmunoassay, like electron microscopy, is not suitable for use in all countries and may need to be replaced when other methods of diagnosing specific virus infections are found.

Though antibody detection by ELISA (except for IgM) cannot strictly be considered as a rapid diagnostic technique, its ease of performance and its excellent correlation with conventional serological tests justified its inclusion.

Among the six figures presented in the manual are step-by-step descriptions of ELISA methods for antibody and antigen assay. Details of the materials and methods used for performing the ELISA technique are annexed, and the manual includes a list of 41 references.

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DRUG INDUSTRY

General News

Multinationals would be allowed to enter high technology areas

The Government has decided to allow drug multinationals to operate only in those areas where either indigenous know-how is not available or Indian sector is not coming forward to manufacture a particular drug, according to Mr. Veerendra Patil, the Minister for Petroleum and Chemicals.

The Union Minister told the Rajya Sabha that the Government was all out for the growth of Indian drug sector. In fact, IDPL was free to import high technology know-how for the manufacture of the latest drugs.

Answering a number of questions, the Minister said, multinationals are resisting the move to market drugs under generic names taking the plea that they maintain high manufacturing standards while others produce only below standard drugs. When a member of Parliament referred to the findings of several commissions of the US Senate that under the guise of technology transfer, only third grade technology was being exported, he stated that the Government carefully examines and screens all applications made by multinationals.

According to the Minister, the working group on drugs and pharmaceuticals had indicated that the additional investment needed during the five-year period starting from 1979, for attaining the estimated requirement of bulk drugs, was about Rs. 370 crore. The total outlay approved during 1978-79 and 1979-80 was about Rs. 180 crore. The bulk drug production had increased from Rs. 130 crore in 1976-77 to Rs. 200 crore in 1978-79.

The Minister also informed the house that during 1979-80 the amount of foreign exchange involved in the import of bulk drugs through State Chemicals and Pharmaceuticals Corporation was Rs. 21.18 crore and was expected to be Rs. 23 crore in 1980-81. This was in addition to the imports by actual users. He said the aggregate outlay contained in the investment proposal for the drug industry in 1978-80 totalled Rs. 130 crore.

Drug units allowed to expand streptomycin capacity

Mr. Veerandra Patil, Minister for Petroleum and Chemicals told the Lok Sabha that Government has decided to import 25 metric tonnes of streptomycin to make up the shortfall in the domestic production. It has also been decided to allow the existing streptomycin manufacturing units to expand their capacity, if they so desired. Shortfall has occurred due to a long strike in the Hindustan

Antibiotics Ltd. Besides HAL, three other firms are manufacturing the drug.

Production of chloramphenicol powder, erythromycin stearate, DDS (dapsone) and chloroquin phosphate during 1979-80 has also fallen as compared to the previous year. However, in respect of formulations based on these bulk drugs, there is no shortage. The reason for shortages include power cuts, labour unrest and non-availability of some of the raw materials like ethylene oxide, caustic soda, etc. The Government is regularly monitoring the availability of such drugs and as and when some shortage in any area is noticed steps are taken to rush supplies there.

Drugs prices steady

The prices of essential life-saving drugs have not increased since March 1978, Mr. Veerendra Patil told the Lok Sabha recently. He said though no report of disappearance of any essential drug has come to the Government, shortage of some brand products were reported occasionally. However, equivalent products were generally available in these areas.

The prices of drugs are, on the whole, steady for the last four years. In fact the whole-sale price index had marginally declined from 136.3 in 1977-78 to 136.61 in 1977-78, 136.1 in 1978-79 and 135.1 in 1979-80. Mr. Patil said that drug manufacturers had represented, individually, as well as through their associations for an increase in the prices of drugs and formulations consequent up on the escalation in the input cost, particularly after the increase in the prices of petroleum products in August, 1979. But, he said, any price revision is possible only after finalisation of the procedure and principles for price revision.

BICP recommends cutback in bulk drug prices

The Bureau of Industrial Costs and Prices has recommended sharp cutback in the prices of several bulk drugs which will affect mostly the private sector pharmaceutical companies.

BICP has worked out a price of Rs. 101.04/gm for betamethasone alcohol made by Glaxo Laboratories against the existing price of Rs. 134.28. Similarly for betamethasone valerate and betamethasone disodiumphosphate the prices suggested are Rs. 94.71/gm and Rs. 112.43/gm respectively against the ruling prices of Rs. 220/gm and Rs. 225/gm.

Hoechst's glybenclamide is to be brought down to Rs. 1489/kg from the existing price of Rs. 9800/kg. Its another drug baralgan ketone has been priced at Rs. 1700/kg against the existing price of Rs. 8019/kg. But some private companies have been benefited also. The price of aspirin made by Alta Laboratories has been recommended to be jacked up from Rs. 24.58/kg to Rs. 26.36/kg. Similarly insulin made by Boots Company has been recommended a higher price of Rs. 13858 per MU against the current price of Rs. 13367 per MU.

Bulk drugs made by IDPL have also been recommended price hike. Vitamin B_1 of IDPL has been offered a price of Rs. 694.15/kg against the present Rs. 666.31/kg. Similarly for sulphacetamide the price hike suggested is

Rs. 148.94/kg from the existing Rs. 102.25/kg.

Impact of drugs price mark-up to be assessed

Bureau of Industrial Costs and Prices has been asked by a Cabinet sub-committee on drugs to estimate within 10 days the implications of applying mark-ups for Categories I and II drug formulations. The sub-committee was in a fix as it found it difficult to recommend price increases in a few cases and to abide with BICP's suggestion for reductions on certain other formulations.

The drug manufacturers have already made it known that they will be in loss if the mark-ups recommended in DPCO are implemented for all drugs falling in Categories I and II. The mark-ups for these categories are 40 and 55 per cent respectively.

The sub-committee proposes to take a total view of the situation in the light of escalation in costs and the Lavraj Kumar committee reports on excessive profits by the major pharmaceutical manufacturers. The Kumar committee had concluded that 62 per cent of companies had average post-tax return of 14 per cent for the past 10 years in their total manufacturing activities.

Foreign companies want disinvested shares for public

Foreign drug companies have urged Mr. Veerendra Patil, the Union Minister for Petroleum and Chemicals, to allow them to offer their disinvested shares to the public or other potential investors as they might deem fit. The companies have expressed their opposition to public financial institutions acquiring two thirds of the disinvested shares as stipulated in the new drug policy.

Several multinational drug companies will be entering in the share market as soon as Reserve Bank of India takes a decision on permissible limit of foreign equity.

The industry is also perturbed over the reported move of the Government to freeze production capacities on the basis of highest production actually achieved during the three-year period ending March 31, 1977. The plea to reconsider this step was turned down by the Secretary of the Ministry of Chemicals and Fertilizers on the ground that compound growth over licensed capacities would nullify the whole basis of industrial licensing. However, the Secretary said cases of technological improvement without the installation of additional machinery would be sympathetically considered.

According to industry, such regulation of capacities should be done at the levels of installed production capacities of the various units. Any curb to cut production would result in increasing the idle capacity of the production facilities already created.

Drug units seek relief on sugar and petroleum products

A joint appeal has been sent to Mr. Veerendra Patil, Union Minister for Petroleum and Chemicals by a representative organisation of the drugs and pharmaceutical industry to grant some interim relief for the critical situation arising out of the recent sugar and petroleum products hike. Sugar is costing around Rs. 7 per kg, while petroleum products have become abnormally costlier. The "Leader Prices" are unreasonable as they are determined on the basis of the products of "major" manufacturers.

Duty exemption for life saving drugs suggested

Mr. B. Shankaranand, Union Minister for Health and Family Welfare, while addressing the Consultive Committee of the parliamentarians attached to his ministry agreed to their suggestion to take up with the authorities the issue of exempting customs duty on imported life saving drugs. He said, a provision already existed under which such drugs could be exempted from custom duty if the Director General of Health Services certified that a particular drug was not available in the country.

The Committee Members expressed their concern over increase in drug prices and wanted that these drugs be made available at a reasonable price.

Drug Act enough to punish spurious drug makers

The Minister of State for Health, N. R. Laskar told the Parliament that there is no proposal to use the Preventive Detention Act against the manufacturers' of fake drugs. He said the provision under the Drugs and Cosmetics Act are adequate for taking actions against persons indulging in manufacture of fake drugs.

Harmful drugs for the third world

Mr. Anwar Fazal, President of the International Organisation of Consumers Unions has criticised the developed countries for exploiting the third world countries by selling them the harmful drugs banned in their own countries. The users in the underdeveloped world are not aware of the risks involved in consuming these drugs.

IMA opposed to drugs price hike

The Indian Medical Association has resented the plea reportedly made by the drug manufacturers to Union Government to raise the prices of drugs. According to the association, the prices of the drugs were already high and a further rise would put life-saving drugs beyond the reach of the common man. The main reason for the price rise was the competition among manufacturing firms.

The Association pleaded for the implementation of Hathi Committee report which has recommended that 117 essential drugs be made available at subsidised rates.

Doctors resent brand name abolition

Association of Physicians of India and Federation of Obstetrical and Gynaecological Societies of India in separate representations to the Union Ministry of Health and Family Welfare have resented the Government's move to switch over to generic names of drugs. According to Dr. C. R. R. Pillay, President of API, the step is retrograde and dangerous to both the profession as well as the patients. Government should have sought the opinion of various scientific associations before taking any action.

Drug industry not satisfied with price relief offer

The drug industry associations namely OPPI, PAMDAL, IDMA and others have objected to certain modalities in calculating the price relief to be offered to the industry for bulk drugs and formulations.

They have objected to Government's freezing the expense on bonus at the statutory minimum of 8.33 per cent even in units which are paying much more. Government has also calculated the return on net worth on depreciated capital value and taken the lowest cost at which any one of the competing units is selling its raw materials to the industry.

The associations have pointed out that under the above conditions the relief will be too inadequate and will not solve their financial crisis. The associations have demanded the mark up at break even level of 75 per cent beginning with category I. According to them the manner in which BICP has calculated the cost of bulk drugs, taking into account the installed capacity of the manufacturing units, is also not fair when the present utilization is far below the installed capacity.

Too many Indian doctors in developed countries: WHO study

A multinational study conducted by World Health Organisation has revealed that India is the biggest donor of doctors to the developed countries. A total of about 15,000 doctors, mostly MDs, are working abroad which amounts to 13% of the country's total. These doctors mean a total investment loss of $ 144 million to India and this money could have been better utilized in other forms of health personnel and health care.

According to the study, the developing countries turn out far more doctors than they can afford to employ. Migration, therefore, is inevitable. 'The situation is just the opposite in developed countries. India with a per capita income of about $ 120 and a growth rate of 1.5 per cent needs only 35,000 doctors. As the vast majority of Indians can not possibly pay for private care about 80,000 to 1,00,000 doctors are rendered surplus.

The study also points out that the courses run by Medical Council of India were international in scope and do not cater to the needs of the country. The Indian medical colleges mostly identified themselves with highly expensive urban oriented and curative western medicine producing specialists with qualifications far removed from the actual needs.

The steps advised in the study to regulate this out flow are: 1. Produce just as many doctors as the country can afford; 2. Plan for numbers and categories of health personnel; and 3. Match the education and training programme to the country's priorities.

Efforts to check this migration by withholding passports, banning foreign qualifications and forcing doctors to work in hardship areas would, however, not succeed but on the other hand will create discontent and illegal migration.

US Supreme Court grants patent to artificially created form of life

A patent application filed by Dr. Ananda M. Chakrabarty of General Electric on 7 June 1972 concerning a form of **Pseudomonas** *bacterium produced by genetic engineering techniques for digestion and dispersal of oil slicks was finally granted by the US Supreme Court. The Patents Office had refused to grant the patent saying that all manifestations of nature are free to human race and under existing US laws it does not have the power to grant patents on living things. The issue was taken to US Court of Customs and Patents Appeals (CCPA) which ruled in favour of General Electric and directed the Patents Office to grant the patent. However, Patents office asked for a reconsideration of the decision. The CCPA upheld its earlier decision and the case eventually went to Supreme Court which ruled that Dr. Chakrabarty's invention was no natural phenomenon but is the result of human ingenuity and research.*

The Supreme Court in a majority judgement of five votes to four ruled that "a live, human-made micro-organism is patentable subject matter as it constitutes a manufacture or composition of matter covered by Federal Patent laws".

The new oil eating micro-organism developed by Dr. Chakrabarty degrades crude oil into carbon dioxide and proteins. It differs substantially from various naturally occurring organisms which can oxidise only a few kinds of hydrocarbons found in crude oil. The new **Pseudomonas** *microbe was created in the laboratory using recombinant DNA as well as conventional techniques used in bacterial genetics. This microbe is going to combat environmental pollution caused by oil spills and wastes as it would eat up this floating (garbage).*

The immediate impact of this decision will be felt by about 100 patent applications pending with US authorities mostly using recombinant DNA techniques. Some of the pending applications are for the production of human growth hormone, insulin, and thymosin and the anti-viral agent interferon. But an application, the outcome of which is much awaited, is one filed in 1974 jointly by Stanford University and the University of California, on hehalf of Drs. Stanley Cohen and Herbert Boyer seeking a patent on some of the most basic techniques of gene splicing. If this patent is granted it is presumed that most of the companies will have to obtain licences from Stanford and pay royalties to both the universities.

Decision on regularisation of excess drug out put soon

A decision on regularisation of excess drug production will be taken soon. The Government is collecting information about the licensed capacities, actual production etc. of individual units. A recall of all industrial licences, carry on business licences and other permission letters issued to the units is in offing. A possible amendment of the Industrial Development and Regulation Act may also take place for induction of any new conditions in the industrial licences already issued.

Excess production of formulations falling within the decontrolled category is unlikely to be regularised. Such units may revert to the production at the authorized level only. Excess production of household remedies produced by foreign drug companies may not be regularised. Hathi Committee had recommended rogularisation of excess capacity on the condition that they are manufactured from the basic stage and half of the production of basic drugs is made available to non-associated Indian formulators. Regularisation now, it is hoped, will be on the basis of highest production actually achieved in any year during the three year period ending March, 1977.

WHO to help Zambia in combating sleeping sickness

The Zambian Government and WHO Tropical Diseases Research Centre at Bdola are collaborating to fight trypanosomiasis commonly known as sleeping sickness. A joint research programme to study the characteristics and prevalence of the disease will also be carried out. The WHO estimates that millions of people and cattle in Africa are open to the risk of contracting sleeping sickness and an unknown number die of the disease every year.

2,4,5-T runs into hot weather in Britain

The use of herbicide (2,4,5-Trichlorophenoxy) acetic acid has become a bone of contention between different governmental agencies in Britain. Representatives of the British Trades Union Congress sitting as members in Health and Safety Executive's Advisory Committee on Toxic Substances have called for a ban on 2,4,5-T because of its teratogenicity. The union representatives have expressed their concern over the large scale use of this herbicide, particularly by forestry department.

The strong criticism of this herbicide has forced the Advisory Committee on Pesticides (PAC) of the Ministry of Agriculture, Fisheries and Food to review the herbicide for the ninth time in light of last two years' published information about 2,4,5-T and its dioxin (2,3,7,8-tetrachlorodibenzo-*p*-dioxin) contaminant.

The review sub-committee has told that dioxin content of 2,4,5-T now at a maximum of 0.01 ppm is so low that it poses no threat, dioxin is carcinogenic at the dose of 0.1 μgm/kg body weight per day in rodents. Rodents would therefore need 2,4,5-T about one tenth to a half of their body weight to consume such a quantity of dioxin. The herbicide itself is a teratogen in some rodent species at a concentration of 35 mg/kg body wt, 10,000 times the concentration at which dioxin is a teratogen.

The review sub-committee's recommendations are now to be considered by PAC.

Nature, **286,** 97 (10 July 80)

Bureaucracy delays new drug introductions: UK report

The Office of the Health Economics, London, has warned in its latest report "*A Question of Balance: The Benefits and Risks of Pharmaceutical Innovation*" that bureaucracy is obstructing innovation in the British drug industry. At present it takes ten years for a drug to come in the market from the time of its synthesis. The administrative delays by agencies that monitor drug safety are painfully long: on an average 25 weeks for permission by the Committee on Safety of Medicines for clinical trials and 56 weeks for getting permission to market a new drug. The prolonged time to satisfy drug regulatory agencies in different countries and complexity of the tests required are thus making research on drugs for treating rare diseases completely uneconomical.

The report suggests that time and money spent in drug testing would be acceptable if evidence showed that safer drugs were being produced. But all drugs are potentially toxic, and by applying even today's effective toxicological testing some side-effects remain undetected because they are totally unexpected and have a very low incidence. The Committee on Safety of Medicines, which banned antihistamine methapyrilene on grounds that in rats its 25-30 times the dose appropriate to man, produced tumours, has been criticised by the report. In such cases potential benefits need to be weighed against the risks.

Professor George Teeling-Smith, the author of the report, has called up on the Government to re-examine the usefulness of the tests required before a drug is marketed. He suggests post-marketing surveillance as an alternative. Since the main problem lies with the public attitude towards risks, a better-informed public could help policies move towards rational solutions.

British Medical J., **280,** 1484 (21 June 80)

German medical association favours drug samples

The West German Medical Association has passed a resolution demanding the continuation of free distribution of drug samples to doctors. This is in contrast to an earlier resolution by the West German Pharmacists Association (BPI) which had demanded a ban on free drug samples to doctors (*See* this bulletin, Vol. 3, No. 1, p 15). The doctors support their demand by giving the following reasons:

1. Doctors need to be familiar with the shape and pack appearance of a product to be able to advise his patients;

2. Precise knowledge of the colour and appearance of product will enable doctors to estimate which drug has been taken in cases of overdosing where no pack can be found;

3. Where the patient has difficulty in taking the product the doctor should have the product's sample in order to explain what is necessary;

4. In case of any suspicion about the formulation doctor can check using the sample pack;

5. The doctor must be familiar with the pack insert and be able to explain its contents to his patients;

6. For the hypersensitive patient the doctor must be able to test tolerance by means of a sample pack;

7. Patient's intolerance or interaction to other drugs, food, tobacco or alcohol can be tested by administering doses from a sample pack; and

8. A supply of drugs is a good way to make the doctor aware of the quality and range of his prescribing habits.

Scrip, No. **496**, 5 (11 June 80)

Unique life system found in deep ocean

In one of the major oceanographic finds of the decade, a unique self-contained ecosystem has been discovered in the Galapagos rift zone of USA at a depth of one and a half mile below the ocean surface. The huge blood-red tube worms, fish crabs, clams and mussels were found to grow without light and draw their energy from bacteria that metabolize hydrogen sulfide dissolved in the spring waters. This discovery has been located in the vicinity of hot springs of the mid-ocean ridge which itself was discovered in 1977.

Analysis of the water from Galapagos has shown bacteria count between 1 million and 100 million organism per cc. Many of these organisms cannot grow in the cold ambient water. Many grow at up to 150°F and some were found even at 212°F. Since these bacteria are the primary food for the nearby animal communities they are thought to be growing at phenomenal rate. Evidence has also come up of some organisms with big membrane system characteristic of bacteria that oxidise methane and ammonia.

This discovery could become the basis of a new form of aquaculture in which industry's waste hydrogen sulphide would be converted to edible clams.

Chemical & Engineering News, **23**, (24 March 80)

Prisoners in US oppose ban on their use in drug trials

US Food and Drug Administration's ban on the use of prisoners in drug clinical trials has run into unexpected opposition from prisoners. Many of them do not want financial rewards but feel that participation in such drug trials will in a way repay to the society for the crimes they had committed.

Scrip, No. **500**, 9 (25 June 80)

Danish pharmaceutical output \$. 393 million

Pharmaceutical production in Denmark in 1979 increased by 18.4% over the 1978 figures. Out of the total production of \$. 393 million, 76% was exported, the largest export being of insulin (\$. 93 million). The second largest was vitamins (\$61.9 million). The imports increased by 16% to \$. 187.5 million and were mostly from W. Germany and UK. Denmark had by the 1979 end, 2201 pharmaceutical products in 3824 formulations.

Scrip, No. **500,** 4 (25 June 80)

USP/NF combined under one cover

The twentieth edition of United States Pharmacopeia and the fifteenth edition of the National Formulary have been combined under one cover under the title USPXX-NFXV. The standards which become official from July 1, 1980 are obtainable from United States Pharmacopeial Convention, Distribution Department, 29th and Northampton Streets, Easton, Pennsylvania 18042 USA.

Company Reports

ICMA annual general meeting highlights

The 39th annual general meeting of the Indian Chemical Manufacturers' Association was held in Bombay on June 4, 1980. Mr. Veerendra Patil, Union Minister for Petroleum, Chemicals and Fertilizers who inaugurated the meeting said that the Government was keen on maximum utilization of coal tar produced in India so that high cost of indigenously produced intermediates and chemicals could come down. Setting up of large economic size plants to produce intermediates and chemicals is also being considered. To increase the availability of basic chemicals like benzene, toluene, xylene and olefin based chemicals, aromatic complexes and gas crackers would be set up based on Bombay High gas.

Earlier Dr. R. J. Rathi, President of ICMA in his presidential address suggested reconsideration of the concept of export obligation, banning of export of alcohol and its products and making of provisions of advancing loan on soft terms for undertaking anti-pollution measures.

Alembic Chemicals sales increased marginally in 1979

The total sales of Alembic Chemical Works Co. Ltd. increased from Rs. 33.76 crore to Rs. 34.79 crore during 1979, a very marginal increase in term of results but significant otherwise, considering the fact that the company manufactures mostly bulk drugs and formulations falling in Categories I and II for which prices are frozen at levels where losses are inevitable, according to Mr. R. B. Amin, Chairman of the Company. Addressing the annual general meeting of the company Mr. Amin further said that while implementing the Drug (Prices Control) Order 1979, prices of essential drugs were reduced instead of being raised. He said that it had become difficult to maintain production because of the above factors as well as shortage of raw materials like streptomycin and procaine hydrochloride and packing material.

Mr. Amin wanted the Government to immediately take the following steps to improve the situation: (a) Replacement of drug pricing system by a monitoring agency in which representative of industry should be included; (b) Reduction in import duty on all drug intermediates; (c) Implementation of Chavda Committee recommendations; (d) Encouragement of R&D activities by allowing duty free imports of equipment, etc.; (e) Abolition of licensing controls and constraints on production; and (f) Revision of present tax system and replacement of excise duty by value-added tax.

German Remedies to raise sulfinamide production

The German Remedies has been issued an industrial licence to expand its basic sulfinamide production. The expanded capacity is expected to be commissioned by October, 1980. The company is setting up a plant for the manufacture of chemical and bulk drugs at Patalganga, a backward area of Maharashtra.

This was stated at the annual meeting of the share-holders in Bombay by Mr. H. J. Voss, Chairman and Managing Director of the company. Sales during the first five months of the current year were about 21 per cent more compared to the same period last year. The company's products are in good demand and future prospects appear to be good though profitability might be affected due to the uncertain world economy and escalation in production costs, according to Mr. Voss.

Pfizer to set up drug unit in W. Bengal

The US drug firm, Pfizer has finalised a collaborative agreement with W. Bengal Government to set up a drugs factory at Kalyani, according to Dr. Kanai Lal Bhattacharya, West Bengal Minister for Industries.

Punjab to set-up three drug units

Indian Drugs and Pharmaceuticals Ltd. will provide technical and financial assistance to Punjab State Industrial Development Corporation in setting up three major drug units in the State.

The first unit costing about Rs. 8 crore will be located near Sangrur, a maize growing area and will manufacture glucose, dextrose and starch from maize. The plant is expected to be commissioned by October this year. Project reports have also been cleared for the second plant which will make vitamin C. Third unit to be put in Derra Bassi is a Rs. 2 crore formulation plant. IDPL has agreed to prepare a scheme to set up some basic drug units in this area to feed the formulation plant.

Poor show by public sector drug firms

A *Business Standard* survey has revealed that the performance of the two public sector drug manufacturers namely, Indian Drugs and Pharmaceuticals Ltd. and Hindustan Antibiotics Ltd. was disappointing during the period 1978-79. IDPL's total sales were Rs. 73 crore and the gross profit was Rs. 7.3 crore but the net profit amounted to only Rs. 2 lakh. The total sales of Hindustan antibiotics amounted to Rs. 16.43 crore during 1978-79. The net loss was Rs. 1.97 crore. Hindustan Organic Chemicals fared better as they earned a net profit of Rs. 4.26 crore against the total sales of Rs. 25.22 crore.

Vicco Laboratories get Malta Government award

Mr. and Mrs. Pandharkar of Vicco Laboratories will receive on behalf of the firm an international trade trophy from the President of the Republic of Malta in recognition of the progress made by the Vicco in the small-scale sector in competition with the multinationals.

Vicco Laboratories are the manufacturers of ayurvedic herbal medicines in the small-scale sector and have started exporting its products to US and Europe.

Ranbaxy performance encouraging: Chairman's report

Addressing the Annual General Meeting of the Ranbaxy Laboratories, its Chairman Bhai Mohan Singh, said that performance of the company in 1979 was very encouraging in spite of the country having a very uncertain economic climate. The turnover in 1979 was Rs. 13. 5 crore which is about 25% over the preceding year.

Bulk drug production formed 30% of total turnover and saved the country of Rs. 50 lakhs worth of foreign exchange. In terms of essential formulations, through these life saving drugs the value generated is around Rs. 10 crore, according to the Chairman.

The company has increased its antibiotic range by adding two more formulations, sporidex (Cephalexin) and spordine (Cephaloriwine). The additional formulation block at the company's plant in Okhla (N. Delhi) has already started working. More products are expected to be introduced in 1980 in the herbal cosmetic range.

Exports during 1979 were Rs. 101 lakhs against Rs. 52 lakhs in the previous year. The joint venture project of the company in Nigeria has already started production.

During the first 5 months of the current year a growth of more than 10% over the corresponding period of last year has been observed. A new plant for manufacturing bulk 'Doxycycline' is also expected to be commissioned this year. The chairman also announced the issuance of bonus shares in the proportion of one equity share for every existing equity share.

Research and Development

CFTRI extracts Vitamin E from wheat germs

A process for the extraction of an oil from wheat germs has been standardized by Central Food Technological Research Institute, Mysore. The oil is used for the production of vitamin E. The germ constitutes about 2.5 to 3.6 per cent of wheat and from 100 gm of germs, 50 mg of vitamin E and 6.7 to 9 per cent oil are obtained during wheat milling germs get mixed with bran which is used as animal fodder. A private firm which had sponsored the project will now use this process for extracting vitamin E.

European firms developed 11 major drugs for tropical diseases in ten years

UNIDO Preparatory Meeting to the 1st Consultation on the Pharmaceutical Industry, held in Cancun, Mexico, was told by Dr. Arnold Worlock that the European pharmaceutical companies have developed 11 major drugs for tropical diseases in the past ten years. These drugs are: Anthemal (sulfamethopyrazine) an antimalarial from Rhone Poulenc; Arilvax, a yellow fever vaccine from Wellcome; Bilarcil (metrifonate) a schistosomicide from Bayer; Fansidar (sulphadoxine+pyrimethamine) an antimalarial from Roche; Fantorin (stibophen) a schistosomicide from Winthrop; Flagentyl (secnidazole) an amoebicide from Rhone poulenc; Jonit (bitoscanate) an anthelmintic from Hoechst; Lampit (nifurtimox) an anti-chagas from Bayer; Lampren (clofasimin) an antileprotic from Ciba-Geigy; Maloprim (pyrimethamine+dapsone) an antimalarial from Wellcome; and Randanil (benznidazole) an anti-chagas from Roche.

Scrip, No. **496,** 12 (11 June 80)

New vaccine for herpes developed

A new vaccine prepared by Dr. Gordon Skinner of the Birmingham School of Medicine has given hope to provide a cure for herpes genitals, herpes simplex II and herpes encephalitis. Made out of herpes viral antigen, the vaccine has no side effects.

The vaccine was prepared by cultivating the virus in a culture of cells prepared from the lungs of human embryos. The culture cells were broken up with ultra-sound and the virus floating in the medium was treated with detergent. This liberates the antigen from the surface of the virus which partly kills the virus itself. Any remaining viral genetic material is destroyed by adding formaldehyde and antigen is removed by high speed centrifugation through sucrose.

New Scientist, **85,** 479 (14 Feb. 80)

Rifampicin likely to be produced in Japan

Rifampicin whose patent by Dow Lepetit expires in 1982 is to be produced by a number of Japanese firms. Companies already in a process to receive approvals for import or to produce bulk material are: Sawait Seiyaku—depending on bulk import of rifampicin from Chemimport of Rumania; Kanegafuchi Chemical—inclined to use its our technology; and Kaken Chemicals—depending on supplies from Kanegafuchi.

Scrip, No. **498,** 6 (18 June 80)

Vitamin toxicities

Irrational use of vitamins often leads to rare but severe results. *Vitamin A* in single dose greater than 12,000 iu/kg may induce anorexia, nausea, vomiting and headache. In India where doses of 200,000 iu are given every 6 months, 3-4% patients suffer from above symptoms with also the possibility of a rise in CSF pressure lasting for a few days. Severe overdoses cause pruritis erythema, skin desquamation, inflammation of the tongue, lips and gums and loss of hair. Toxic manifestations could be avoided by giving 5000 iu/kg for not more than 200 days, with intervals between courses ranging 4-6 weeks. Aqueous emulsions are more likely to cause toxic effects than the oily preparations. For skin ailments or cancer, retinoic acid, not retinol, should be given as it has no liver toxicity. *Vitamin D* induced hypercalcemia is important from the point of view of drug selection. Ergocalciferol (vitamin D_2; calciferol) and cholecalciferol (vitamin D_3) induce hypercalcemia slowly but their effect is prolonged, whereas dihydrotachysterol and alfacalcidol act rapidly. Alfacalcidol is the safest because after its withdrawl serum calcium quickly reverts to normal.

Adults given 100,000 iu of vitamin D regularly may develop weakness, nausea, vomiting, dehydration and metastatic calcification. In children sensitive to vitamin D in fortified dried milk it causes idiopathic hypercalcemia, *Vitamin E* taken 600 iu daily raises serum triglycerides in women and lowers thyroid hormone levels in both sexes. *Vitamin K* produces cutaneous reaction at the site of injection. Doses greater than 10 mg in neonates lead to adverse reactions. *Nicotinic acid* doses in 3-10 g daily, recommended to treat hypercholesterolemia, cause flushing of face, neck and chest and itching. Peptic ulcers get worsen. *Thiamine* should be skin tested in those with past history of allergy. It causes reaction at the site of injection which is infrequent and unpredictable.

Ascorbic acid in doses above 4 g daily increases uric acid and oxalate excretion in urine. Edema, rashes have been reported and in G-6-PD deficient persons it may lead to severe hemolysis. A "Conditioned need" is induced by the vitamin C intake which results into hypovitaminosis when the vitamin is stopped. *Folic acid* given in large doses makes seizures more difficult to control in epileptics. In patients with megaloblastic anemia from Vitamin B_{12}deficiency, folic acid can precipitate neurologic complications by hastening depletion of Vitamin B_{12} stores.

Inpharma, No. **242**, 2 (21 June 80)

Of corticosteroid/antibiotic combinations

The efficacy of corticosteroid/antibiotic combinations has been debated for years because of the difficulty in comparing them with corticosteroids alone. The constituants in combinations give rise to problems such as corticosteroid atropy, contact allergic sensitization and induction of resistant organisms. However, in some occasions combinations may be used with benefits too. In eczematous skin which is prone to infection by *Staphylococcus aureus,* antibiotic is useful in prulent, crusted lesions. Lesions resistent to corticosteroids may also clear after addition of antibiotics. In noneczematous skin, combination may be used in clinically infected lesions. Repeated application should be avoided in statis eczema, intertrigo, napkin dermatitis and other inflammed skin conditions. However, no antibiotic neomycin, gentamycin, chlortetracycline and gramicidin is totally free of risks of contact sensitization. Potent corticosteriods should also be avioided on the face, flexures and thin intertriginous skin.

Inpharma, No. **240,** 3 (7 June 80)

Nufenoxole: Antidiarrhoeal without opiate dependence

Nufenoxole (SC 27166; Searle) a new antidiarrhoeal has been found to have no opiate dependence liability. A study involving ten patients revealed that this agent produces no opiate-like effects on pupil diameter, B. P., pulse or respiration rate.

Inpharma, No. **243,** 8 (28 June 80)

Gold salt good for juvenile rheumatoid arthritis

The US Food and Drug Administration recently approved the treatment of patients suffering from juvenile rheumatoid arthritis with gold salts. 63 patients were treated with sodium aurothiomalate which reduced the severity of articular manifestations in 32 of the 51 treated for six months. The total number of involved joints reduced in 25 patients. A few of these 63 patients who had nitritoid type reactions were given aurothioglucose. Most patients took one non-steroidal anti-inflammatory agent also. Side effects were not much except in 5 patients where treatment was discontinued.

Inpharma, No. **243,** 11 (28 June 80)

US physicians warn against interferon usage in cancer

According to a report published in *Washington Post*, leading cancer experts in USA have agreed to warn their patients that so far interferon is found to be far less impressive than they had earlier hoped. Due to extensive publicity of interferon, people are buying it at whatever cost they could get. Although interferon may eventually prove useful, it is quite premature to evaluate its efficacy, according to a leading physician. The American Society of Chemical Oncology has supported this move by stating that no evidence is available that interferon may cure advanced cancer or can extend patients' lives regardless of the type or stage of cancer. Moreover, many other approaches to treatment of cancer, currently under investigation, have produced equally favourable results than interferon.

Scrip, No. **500,** 9 (25 June 80)

Japanese anticancer drug to be marketed

Aclacinomucin a drug found to be remarkably effective in controlling and in some cases curing stomach, lung and breast carcinomas, malignant lymphoma and leukemia is to be marketed by Yamanouchi Pharmaceuticals. According to Sansaku-Ocean, the manufacturers, the drug has fewer side-effects than conventional anticancer products.

Pharmaceutical Technology International, No. 3(2), 36 (April 80)

REGULATORY NEWS

Gentamicin to be reserved for systemic use only

Pharmaceutical manufacturers have received a circular form Drug Controller of India eliciting their comments on a proposal that seeks gentamicin to be reserved for systemic use only. The circular of the Drug Controller points out that most of the dermatologists are of the view that gentamicin should be avoided for topical use, as it may induce sensitisation against future systemic use.

Excise duty exemption for 30 essential drugs

Union Finance Minister Mr. Venkataraman while presenting the 1980-81 budget announced the exemption of excise duty from 30 life-saving drugs: penicillin, chloramphenicol, tetracycline, streptomycin, insulin, tolbutamide, PAS, ethambutol, hydroxyquinolines, metronidazole and dapsone etc. The list would be kept under periodic review for adding more items, if necessary.

However, the Finance Minister announced the reintroduction of a special excise duty (1/20th of the basic duty of 12.5%) for all other drugs. This duty was abolished in 1979-80 budget.

Vitamin C distribution controlled

The Union Government has reintroduced the informal distribution control arrangements on distribution of Vitamin C by manufacturers. The controls were withdrawn in July last year.

Under the arrangements the units will register their vitamin C requirements with the State Chemicals and Pharmaceuticals Corporation of India and obtain their supplies from one or the other indigenous producers on the basis of the release orders issued by the corporation. Ratio for allocations for the three vitamin C producers will now be 55% for Jayant Vitamins, 40% for Sarabhai M. Chemicals and 5% for Hindustan Antibiotic Ltd.

Betahydroxy naphthoic acid transferred to restricted list

In view of the indigenous production the Union Government has transferred Betahydroxy Naphthoic acid from open general licence list to restricted category. The change has been made through a public notice issued by the Chief Controller of Imports & Exports.

Decision on take-over of Bengal Chemicals and Pharmaceuticals soon

The proposal to nationalize the Bengal Chemicals and Pharmaceuticals Works Ltd., is under the consideration of the Government and a decision is likely to be taken shortly. The Union Minister for Petroleum and Chemicals informed Rajya Sabha that allegations of corruption, misappropriation and embezzlement of company's funds and other materials by some high-ups in the management had been looked into but most of them were found not substantiated. Remedial measures wherever necessary have been taken.

Ministry gets more time for granting price approvals

The Drug Controller of India has granted further extension of time up to the 30 September 1980 to drug units for compliance with the requirement of Schedule V of Drugs and Cosmetics Rules. The Ministry of Petroleum, Chemicals and Fertilizers wanted some more time to grant Price approvals in respect of patent or proprietory medicines containing vitamins, the composition of which has been revised to conform to the requirements of Schedule V. The Ministry of Health and Family Welfare accordingly extended the limit.

(*See* This bulletin, **3** (6), 201 (June 80).)

Curbs on drug loan licences in Maharashtra

Maharashtra Government has initiated a move under which irrespective of quantum of production no drug company will be allowed to carry at a time more than 12 loan licences for pharmaceutical manufacturing.

The State Government has taken some other steps also to regulate the loan licences operation in the interest of public health. They are: (1) Number of items limited to 10 for each loan licence in any particular section like tablets, capsules or liquid orals; (2) Every unit manufacturing drugs on behalf of a loan licensee must appoint in each section i.e. tablets, capsules, liquid orals, at least one Government approved person to supervise the manufacturing process; (3) Manufacturers who do not have products of their own will not be permitted to undertake manufacture of similar products on behalf of loan licensees; (4) Adequate number of analysts should be appointed one analyst cannot satisfactorily analyze more than four samples in a day; and (5) Batches of each product will have to be studied for stability after keeping at room temperature for one year. Such data should be furnished to State Government. Failure to do so will result in cancellation of licence.

No levy sugar for drug manufacturers

Food and Drug Administration, Maharashtra has been informed by the Union Ministry of Petroleum, Chemicals and Fertilizers that due to tight availability of sugar, levy sugar allocation to drug industry during current year will not be possible.

Drug manufacturers have resented this order pointing out that the annual sugar consumption of the industry is around 50,000 tonnes which is a fraction of the total sugar consumption in the country. This denial of levy sugar has forced them to purchase the sugar from open market at rates more than Rs. 6 per kg. The sugar based drug formulations have therefore become highly unremunerative. The Drugs (Price Control) Order 1979 calculated the prices of sugar based products on the basis of the levy sugar price of Rs. 2.40 a kg.

In view of the above development the manufacturers are planning to approach the Government as the quantity of sugar involved is too small compared to total annual consumption. The supply of levy sugar will keep up the production and export of sugar based products, otherwise production loss and fall in export are inevitable.

Tetrahydrocannabinol use may be permitted

FDA's Oncology Drug Advisory Committee is considering a recommendation for placing Δ-9-tetrahydrocannabinol in a less restricted investigational category. The National Cancer Institute of USA had suggested that this cannabis drug be made available to a greater number of physicians so as to establish effectiveness of THC as an antinauseant.

PMA Newsletter, **22,** No. 22 (2 June 80)

Drug approval in US a slower process

A study of the Food and Drug Administration's drug approval process by General Accounting Office has concluded that some important drugs, i.e. those providing a major or modest therapeutic gain over any marketed drugs, have been approved faster in other countries compared to US. The report entitled "FDA Drug Approval—A lengthy Process that Delays the Availability of Important New Drugs," has made the following recommendations:

1. Reduce regulation in the early phases of new drug testing; 2. Accelerate approval of breakthrough drugs; 3. Reduce duplicate clinical tests on already marketed drugs; and 4. Restrict distribution of certain drugs that are suited for a controlled environment but which would not be approved for general distribution because of the risks involved.

The GAO committee also wanted the Secretary of Health and Human Services to finally clarify FDA's policy on the acceptance of foreign data.

PMA Newsletter, **22,** No. 23 (9 June 80)

Court rules out reduction in benzene exposure levels for want of adequate data levels

A proposal of the Occupational Safety and Health Administration (OSHA) of the US Department of Labour, calling for a reduction in the permitted exposure levels of benzene to one part per million from the current 10 parts per million, was rejected by the US Supreme Court by a majority judgement of five votes to four saying that strict regulation of toxic substances must be backed-up by adequate scientific data showing potential danger. The OSHA proposal was made after evidence was found that benzene exposure caused various types of blood disorders particularly leukaemia.

The proposed regulations were opposed by the chemical and petroleum industry as unnecessarily restrictive and that the cost of meeting them would be hundreds of millions of dollars which is incommensurate with the expected benefits. The OSHA must demonstrate that a toxic chemical poses a significant risk before making a regulation, the Supreme Court said in its judgement.

The decision came as a big morale booster for the industry but the agency officals, although disappointed, are firm to regulate benzene and other toxic substances.

Nature, **286**, 97 (10 July 80)

Post-marketing surveillance recommended in US

The development of a systematic and comprehensive system of post-marketing surveillance (PMS) has baen recommended in the US by the Joint Commission on Prescription Drug use.

The clinical trials are carried out under conditions which are not consistent with the ultimate use of a drug, for example, too few patients (500-3000), short period or trial (about 2 years) and exclusion of infants, pregnant women, adolescents, the elderly, persons with multiple diseases or those taking several other drugs, are the main inconsistencies. Besides, if trial period and number and variety of patients be increased, the results will remain undisclosed; protracted trials will further delay introduction of new drugs. The Joint Commission emphasizes that PMS system should detect adverse reactions that occur more than once per thousand uses of a drug. The Commission is discouraged to find different rates of voluntary reporting of adverse drug effects by physicians in the US and the UK. The UK "yellow card" reporting system and US FDA "drug experience report" though are not much different, in UK adverse drug effects reports from general practitioners amounted to 50% while FDA got 14% of this information from physicians and 7% from hospitals in 1977. In US, 71% of adverse drug reporting is made by pharmaceutical manufacturers while in UK this is less than 15%. In both these countries manufactures are legally bound to make adverse effects reports. Voluntary adverse effects reports are followed-up routinely in both the countries. But, thd UK method of sending field workers at site to investigate selected instances provides more definitive information than the US methods of further correspondence and telephonic enquiry.

The report also points put that journals in UK carry much more articles and letters on drug reactions than in US. The Commission points out that reports of adverse effects provided by individual physicians though have their importance, the physicians can not detect delayed reactions or often be unable to provide accurate estimate of the incidence. The Commission opines that for PMS research and testing a "centre for drug surveillance" should be operated as a private, non-profit organisation in an academic setting. Funded privately and by the government the Commission proposes the centres budget around $ 110 million.

Inpharma, No. **241**, 4 (14 June 80)

Nifedipine not to be approved by US FDA in near future

A study published in the 5 June issue of *New England Journal of Medicine* reports nifedipine as effective in preventing angina attacks. In treated patients the incidence of attacks dropped from average sixteen to two in a week. The drug appears to act directly to prevent attacks. In some partients, nifedipine produced dizziness, flushing headache and swelling of the feet.

Nifedipine is licensed by Bayer AG to Pfizer for the US Market. But it is not likely to be approved by US FDA in immediate future. Nifedipine was first approved in West Germany in 1975 and is now available in 47 countries.

Scrip, No. **498,** 15 (18 June 1980)

New Japanese standards for stability test

The Japanese Pharmaceutical Affairs Bureau of the Ministry of Health and Welfare has published new standards governing the stability test data required for approval to manufacture or import new drugs into the country. All applications for manufacturing or importation approval submitted after April 1, 1980 should carry long-term and accelerated stability test data.

International Drug Regulatory Moniter, No. **85,** 1 (June 80)

KARNATAKA STATE DRUGS CONTROL DEPARTMENT

(*Monthly Report: April, 1980*)

During April, 1980 drugs worth Rs. 1,780/- were destroyed as they were found to be not of standard quality. A case was instituted under the Drugs and Cosmetics Act, 1940 and three cases under the Drugs (Prices Control) Order, 1970 during this month.

Of various sales establishments 42 licences were cancelled, 86 licences invalidated and 23 licencees warned for having contravened the provisions of the Drugs and Cosmetics Act, 1940.

708 licences of sales and of manufacturing establishments were granted/renewed during the month. 455 inspections were carried out by the Inspectorate staff of the department including hospital inspections.

INDUSTRIAL LICENCES AND LETTERS OF INTENT

Issued During April, 1980

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity		Type, No. of Licence and date
	Licences			*Existing*	*After expansion:*	*Substantial Expansion*
1.	Alembic Chemical Works Co. Ltd., Alembic Road, Baroda.	Baroda	(*i*) Bistrepen 1 dose	90 lakh vial	400 lakh	CIL: 102/80
			(*ii*) Bistrepen 5 dose	for i & ii	30 lakh	dated: 9.4.80
			(*iii*) Bistrepen forte	60 lakh vial	195 ,,	
			(*iv*) Streptomycin 1 g	for iii & iv	125 ,,	
			(*v*) Pencrymycin	5 lakh vials	40 ,,	
			Oxytetracycline HCl IP Injections 20 cc vials	5 tonnes		New article CIL: 109/80 dated: 22.4.80
2.	Shri C. G. Amin, Alembic Chemical Works Co. Ltd., Alembic Road, Baroda.	Baroda	(*i*) Alcyclin pediatric drop	1200 lts (existing) 6,800 lts (after expn)		Substantial Expansion CIL: 114/80 dated: 22.4.80
			(*ii*) Algesin tablets	25 lakh (exis) 775 ,, (after expn)		
			(*iii*) Ephedrex N capsules	50 ,, (exis) 650 ,, (after expn)		
			(*iv*) Vikoryl tablets	100 ,, (exis) 600 ,, (after expn)		
			(*v*) Zeet expectorant	44,000 lts (exis) 636,000 ,, (after expn)		
			Bulk Drugs:			
3.	Fairdeal Corp. Ltd., 142-48, S. V. Road, Jogeshwari, Bombay.	Kolaba	(*i*) Lothalamic acid BP (iacluding its salts)	5 tonnes		New Article CIL: 96/80
			(*ii*) Lopanoic acid BP (including its salts)	5 tonnes		dated: 3.4.80

Contd

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. of Licence and date
			Formulations: (*i*) Lothalamate sod injection (*ii*) Lothalamate meglumine injection (*iii*) Lopanoic acid BP tablets	Corresponding to 70% production of bulk drugs	
4.	Indian Drugs & Pharmaceuticals Ltd., N-12, South Extension, New Delhi.	Hyderabad	(*i*) Tablets of trimethoprim and sulphamethoxazole	50 million Consumption of bulk drugs, 1. Trimethoprim 44 tonnes 2. Sulphamethoxazole 22 tonnes 90 klts	New Article IL: 18/80 dated: 14.4.80
			(*ii*) Calcium borogluconate (25% W/V injectables)	Consumption of bulk drugs, 1. Calcium gluconate 21.7 tonnes 2. Boric acid (analytical grade) 4.5 tonnes	
5.	Standard Organics Ltd., 3-4-540/A & B.Y.W.C.A. Narayanguda, Hyderabad.	Medak	(*i*) 3-Amino 5-methylisoxazole (*ii*) Sulphamethoxazole (*iii*) Trimethoprim (*iv*) Trimethoprim (80 mg) and sulphamethoxazole (400 mg) tablets	35 tonnes 30 ,, 6 ,, Consuming a maximum of 70% of annual production of bulk drugs	New Article CIL: 113/80 dated: 22.4.80
6.	Themis Chemicals Ltd., Plot No. 69, GIDC Industrial Estate, Vapi, Distt. Valsad, Gujarat.	Vapi	(*i*) Suproxil capsule 250 mg (each capsule containing 250 mg amoxycillin anhydrous as amoxycillin trihydrate)	3 million	New Article CIL: 117/80 dated: 26.4.80

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. of Licence and date
			(*ii*) Suproxil capsule 500 mg (each capsule containing 500 mg amoxycillin anhydrous as amoxycillin trihydrate	3 million	
			(*iii*) Suyroxil syrup (each 5 ml containing amoxycillin anhydrous 125 mg as amoxycillin trihydrate)	3 lakh bottles	
7.	Unique Chemicals, Prop. J. B. Chemicals & Pharmaceuticals Pvt. Ltd., Sheth Govind Rao Smriti, 83B & C Dr. A. B Road, Worli Naka, Bombay,	Bharuch	Tinidazole (bulk drug)	20 tonnes	New Article CIL: 118/80 dated: 26.4.80
			Formulations, bulk drugs involved	*Annual capacity in terms of bulk drug (in kgs)*	
8.	Uttar Pradesh Drugs & Pharmaceuticals Co. Ltd., A/5 Industrial Area Kanpur Road, Lucknow.	Lucknow	Thiacetazone	1,650	New Unit CIL: 97/80 dated: 3.4.80
			INH	15,400	
			Acetyl salicylic (aspirin)	33,083	
			Caffeine	1,650	
			Phenacetin	8,250	
			Phthalyl sulphathiazole	27,500	
			Dapsone	509	
			Iodochlorohydroxyquinoline	8,250	
			Pheniramine maleate	275	
			Magnesium trisilicate	5,500	
			Aluminium hydroxide gel	2,750	

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. of Licence and date
			Ferrous sulphate	13,750	
			Paracetamol	2,750	
			Phenyl butazone	220	
			Prednisolone	11	
			Theophylline	1,650	
			Ephedrine sulphate	282	
			Phenobarbitone	90	
			Nitrofurantoin	27.5	
			Aminophylline	220	
			Chlordiazepoxide	14	
			Chlorpromazine	19.3	
			Trifluoperazone	3	
			Ethinyl estradiol	1.1	
			Chloroquin phosphate	138	
			Amodiaquin	688	
			Vitamin C	4,744	
			Vitamin B_1	440	
			Folic acid	55	
			Vitamin B_2	134	
			Vitamin B_6	56.2	
			Vitamin B_{12}	135.3 g	
			Nicotinamide	784	
			Calcium pantothenate	120	
			Vitamin A	8,250 MU	
			Potassium penicillin V	500	
			Neomycin sulphate	27.5	
			Secobarital	11	

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. of Licence and date
			Tetracycline HCl	1,375	
			Oxytetracycline HCI	1,379	
			Mannitol	1,540	
			Dextrose	36,575	
			Pethidine HCI	55	
			Aminophylline	137.5	
			Ergometrine maleate	0.1	
			Noradrenaline bitartarate	110 g	
			Morphine sulphate	2.0	
			Atropine	1.0	
			Colloidal calcium	20	
			Lignocaine	273	
			Hydrocortisone acetate	7.0	
			Testosterone propionate	5.5	
			Procaine HCI	88	
			Progesterone	5.5	
			Oestradiol benzoate	0.6	
			Benzyl alcohol	88	
			Coli-tetracycline	33	
			Nitrofurazone	7.04	
			Iodine	22	
			Methyl salicylate	27.5	
			Magnesium hydroxide	1,279	
			Codeine phosphate	11	
			Piperazine citrate	908	

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. of Licence and date
Letters of Intent:					
1.	Cadila Laboratories, 244 Ghodasar, Maninagar Ahmedabad.	Bharuch	(*i*) Ampicillin anhydrous (*ii*) Ampicillin sodium (*iii*) Amoxycillin trihydrate	20 tonnes 5 ,, 30 ,,	LI: 101/80 dated: 18.4.80
2.	Gujarat Synthetic Drugs Ltd., 8 Adarsh Society, Ankleshwar.	Ankleshwar	Doxycycline	5 tonnes	New Article LI: 96/80 dated: 18.4.80
3.	Gujarat Indl. Investment Corpn. Ltd., 4th floor, Natraj Chambers, Ashram Road, Ahmedabad.	Ahmedabad	(*i*) Ampicillin trihydrate (*ii*) Amoxycillin trihydrate (*iii*) Clozacillin sodium (*iv*) Methicillin sodium (*v*) 6-APA	25 tonnes 22 ,, (for (*ii*) to (*iv*)) 35 MT	New Unit LI: 102/80 dated: 18.4.80
4.	Indian Antibiotics Ltd., 8, Adarsh Society, Ankleshwar	Ankleshwar	(*i*) Ampicillin (*ii*) Semi-synthetic Penicillins (Amoxycillin, epicillin, oxycillin, carbenicillin, methicillin) (*iii*) 6-APA	25 tonnes 24 ,, 50 ,,	New Unit LI: 130/80 dated: 18.4.80
5.	Indian Drugs & Pharmaceuticals Ltd., P. O. Balanagar Township, Hyderabad.	Hyderabad	(*i*) Sulphamethoxazole (*ii*) Formulation in the form of suspension (paediatric 21 klt syrup based on sulphamethoxazole and trimethoprim)	22 tonnes (addl.) 30 ,, (after expn)	Substantial Expansion LI: 124/80 dated: 18.4.80
6.	Orient Pharm Pvt. Ltd., Cathedral Road, Madras.	Chingleput	Diaminodiphenyl sulphone	24 tonnes	New Units LI: 75/80 dated: 14.4.80
7.	The Pioneer Ltd., 20 Vidhan Sabha Marg, Lucknow.	Alwar (Rajasthan)	Ampicillin	18 tonnes	New Articles LI: 122/80 dated: 18.4.80

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. of Licence and date
8.	Ranbaxy Laboratories Ltd., 78 Nehru Place, New Delhi.	Okhla, N. Delhi	(*i*) 3 lakh injectables (ampoules) based on 4,8999 tonnes of ioxitalmic acid bulk drug (*ii*) 75,000 injectables (ampoules) based on 0.828 tonnes of maglumine bulk drug		New Article LI: 143/80 dated: 29.4.80
9.	Sudha Drugs and Chemicals India, Ltd., Kothi No. 26 Sector 9-A, Chandigarh.	Patiala	Ampicillin and its salts	6 tonnes	New Units LI: 98/80 dated: 18.4.89
10.	Themis Pharmaceuticals, Unit No. 2, Vapi, Dt. Valsad, Gujarat.	Vapi	Rifampicin bulk drug	1 tonne	New Article LI: 138/80 dated: 22.4.80

NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	Generic Name	Trade Name	Manufacturer	Country
1.	*Analgesic*			
	Diflunisal	Dolobid	Merck Sharp & Dome	Thailand
	Zomepirac	Zomax	Johnson & Johnson	Switzerland
2.	*Antacid*			
	Sucralfate	Sulcrate	Nordic	Canada
3.	*Anthelmintic*			
	Mebendazole	Vermox	Janssen	Australia
4.	*Anti-androgenic/contraceptive*			
	Cyproterone acetate + ethinyl estradiol	Diane	Schering AG	Thailand
5.	*Antianginal*			
	Nifedipine	Adalat	Bayer	Sweden
6.	*Antiarrhythmic:*			
	Disopyramide	Norpace	Searle	Sweden
7.	*Antibacterial*			
	Cefuroxime	Zinacef	Glaxo	Kenya/ Thailand
	Cefoxitin	Mefoxin	Merck Sharp & Dohme	S. Africa
	Ticarcillin	Ticillin	Commonwealth Serum	Australia
	Pivmecillinam	Selexid	Leo	Thailand
8.	*Antidiarrhoeal*			
	Difenoxin	Rheatrol	Abbott	Thailand
9.	*Antihypercholesterolemic*			
	Probucol	Lurselle	Dow	Thailand
10.	*Antihypertensive*			
	Diazoxide	Hyperstat	Schering Corp.	Sweden
11.	*Anti-inflammatory*			
	Sulindac	Clinoril	Merck Sharp & Dohme	Thailand

Sl. No.	Generic Name	Trade Name	Manufacturer	Country
12.	*Antimanic*			
	Lithium carbonate	Priadel	Delandale	S. Africa
13.	*Anti-migrain*			
	Dihydroergotamine	Dihydergot	Sandoz	Thailand
14.	*Antineoplastic*			
	Dacarbazine	DTIC	Dome	Sweden
	Lomustine	CeeNU	Mead Johnson	UK
	Teniposide	Vumon	Bristol	Sweden
15.	*Antiperspirant*			
	Aluminium chloride hexahydrate	Anthydrol Forte	Dermal	UK
16.	*Antiulcer*			
	Acexamic acid + aluminium phosphate	Plasmutal	Choay	France
17.	*β-Blocker :*			
	Nadolol	Corgard	Squibb	Thailand
	Propranolol	Cardinol	Protea	Australia
18.	*Cardiac stimulant*			
	Dobutamine	Dobutrex	Lilly	Australia
19.	*Debriding agent*			
	Dextranomer	Debrisan	Schering	France
20.	*GI regulator*			
	Metoclopramide	Metamide	Protea	Australia
21.	*Glaucoma treatment*			
	Timolol	Timoptol	Merk Sharp & Dohme	Thailand
22.	*Hypoglycemic :*			
	Gliclazide	Diamicron	Servier	Australia/UK
23.	*Muscle relaxant*			
	Cyclobenzaprine	Flexiban	Merck Sharp & Dohme	Thailand
24.	*Ocular antibacterial*			
	Bekanamycin	Kanendomycin	Meiji	Thailand
25.	*Ocular antiseptic :*			
	Cethexonium	Biocidan	Clin Midy	Thailand
26.	*Topical corticosteroid :*			
	Fluorometholone	FML Liquifilm	Allergan	UK

(Contd.)

Sl. No.	Generic Name	Trade Name	Manufacturer	Country
27.	*Topical corticosteroid/antibacterial*			
	Betamethasone dipropionate + framycetin	Diprosone-F	Schering Corp.	Australia
28.	*Tranquilisers*			
	Clobazam	Urbanyl	Roussel	Kenya
29.	*Uterine relaxant*			
	Albuterol	Salbutamol	Allen & Hanburys	Australia

BOOK REVIEWS

Who Expert Committee on Malaria

Seventeenth Report.
World Health Organization Technical Report Series, No. 640, 1979 (ISBN 92 4 1206403) Pages, 71. Price: Sw. fr. 5.

The Thirty-first World Health Assembly in 1978 endorsed a new overall strategy stressing the need for national political commitment to combat malaria and emphasizing that—while eradication remains the ultimate goal—courses of action leading to its achievement should be determined in each country in accordance with the prevailing epidemiological, socioeconomic, and other conditions. The WHO Expert Committee on Malaria was convened in 1979 with the main task of providing guidelines for the health administrator and health planner on how to plan, implement, and evaluate malaria control programmes at this juncture.

Early part of the Committee's report outlines the objectives of a malaria control programme. Three categories of objectives are identified—ultimate (malaria eradication), intermediate (reduction in endemicity to allow socioeconomic development), and immediate (reduction in transmission in order to reduce morbidity and mortality).

The planning and implementation of control progammes is based on four main tactical variants that may be adopted, singly or in combination, according to the situation in a country or an area of it. The goal of variant 1 is the reduction and prevention of malaria mortality; this may be applied where there is high malaria prevalence, severe clinical illness, low socioeconomic status, and limited experience in the administration of malaria programmes. Variant 2, which may be suitable in similar situations in countries where there is the requisite organizational structure to permit a systematic distribution of antimalarials, is aimed at reducing and preventing both mortality and morbidity due to malaria, with special attention to high-risk groups. Variant 3 has the same goal as variant 2, plus the reduction of malaria prevalence; it assumes greater organizational structure and more trained staff and the application of vector control measures. Finally, the goals of variant 4 are countrywide control aimed at ultimate eradication, keeping areas free after eradication has been achieved, and vigilance in countries that are naturally malaria-free but threatened by the introduction of the disease.

Forecasting, prevention, and control of malaria epidemics are given special attention, as is training in malaria control.

Several recent advances in antimalarial drugs, vaccine development, immunological diagnostic methods, and antimosquito methods (including new biological and genetic approaches to vector control) and the areas in which further research is important are discussed. Lastly, the report deals with international cooperation and coordination in anti-malaria programmes and international surveillance.

□

IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Volume 20: Some Halogenated Hydrocarbons. International Agency for Research on Cancer, Lyons, 1979. Pages, 609. Price: Sw.fr. 60.

This twentieth volume of the IARC Monographs comprises 25 monographs on halogenated hydrocarbons which are used as pesticides and microbicides, as industrial solvents and intermediates, or as flame retardants. Several of the compounds covered in this volume were considered previously: technical HCH and lindane, heptachlor, methoxychlor and mirex; carbon tetrachloride and chloroform; trichloroethylene; and 1,2-dibromo-3-chloropropane. Because new, relevant data on these compounds had since become available the monographs were updated and the compounds re-evaluated.

Halogenated aromatic hydrocarbon pesticides and microbicides have wide application. Their major uses are against insect pests (HCH isomers, chlordane, chlordecone, 1,2-dibromo-3-chloropropane, dichlorvos, heptachlor, methoxychlor, mirex and toxaphene) and as microbicides (hexachlorobenzene, hexachlorobutadiene, hexachlorophene, pentachlorophenol and trichlorophenols). Most of these chemicals, except the tri- and pentachlorophenols and dichlorovos are degraded slowly. Such slow degradation and environmental persistence enhances potential chronic exposure. Human exposure to certain of the halogenated aromatic hydrocarbon pesticides and microbicides results in a body burden of long duration; preferential storage occurs in tissues with high lipid content. The principal source of general human exposure is thought to be diet, although direct exposure is also likely to occur from the spraying of large geographical areas during insect control campaigns. Most of these compounds have also been detected in drinking-water.

The most widely used degreasing solvents among the compounds considered are tetrachloroethylene (also used in dry-cleaning textiles), 1, 1, 1-trichlorethane, trichlorethylene and dichloromethane.

Evaluations of the carcinogenicity in experimental animals of several compounds considered in this volume are based largely on data obtained from the United States National Cancer Institute's Bioassay Program. Among the chemicals considered in this volume, chlordecone, hexachlorobenzene, mirex, toxapnene, carbon tetrachloride, chloroform, 1, 2-dichloroethane, 1, 2-dibromo-3-chloropropane and tris (2, 3-dibromopropyl) phosphate were evaluated as having sufficient evidence of carcinogenicity in experimental animals. For several of the chemicals considered in this volume, the data available were considered inadequate to evaluate carcinogenicity although carcinogenicity studies are in progress on most of them.

This work is of interest to all those concerned with the primary prevention of cancer. □

CENTRAL DRUG RESEARCH INSTITUTE

(Council of Scientific & Industrial Research)

ADVERTISEMENT NO. 3/80

Applications are invited for the following posts for the National Information Centre for Drugs & Pharmaceuticals at CDRI under the NISSAT Plan of Department of Science & Technology, Government of India. These posts are temporary but are likely to continue. The persons selected will be governed by the rules as applicable to CSIR employees.

1. **ASSISTANT EDITOR (SCIENTIST 'B')** : 1 post
(Rs. 700-40-900-EB-40-1100-50-1300)

High academic qualification in Chemistry/Biology/Pharmaceutics with at least two years experience in scientific editorial work with proof of having worked in a reputed organisation bringing out regularly scientific publications. Knowledge of a foreign language besides English as well as familiarity with printing and production techniques will be added qualifications. *Job requirement:* To assist in the production and printing of NICDAP Bulletins.

2. **SENIOR LIBRARIAN** : 1 post
(Rs. 550-25-750-EB-30-900)

Graduate, preferably degree in science with a degree in Library Science and at least 7 years professional experience in a large library of a scientific or industrial organisation. Good knowledge and practical experience of technical processing of books, reports, periodicals, and other documents in a specialised library are essential. *Job requirement* : For taking up the increased load of work of acquisition and processing of documents of the Centre.

3. **SENIOR TECHNICAL ASSISTANTS** : 1 post
(Rs. 550-25-750-EB-30-900)

Diploma in photography and at least 3 years experience in reprography work and maintenance or reprography equipments. Should have thorough knowledge of reprography systems, in particular microfilm/microfiche processing. *Job requirement*: For processing of microfilm/microfiche of documents in the Reprography Laboratory of the Centre.

The posts carry usual allowances admissible under the Central Government rules. Qualifications/experience are relaxable in case of candidates otherwise well qualified/experience and found suitable for the post. Applications for the posts mentioned above on the prescribed form obtainable from the office of the Administrative Officer, Central Drug Research Institute, Chattar Manzil Palace, Lucknow-226001, should reach him not later than 22-9-1980. The application must be submitted with an application fee of Rs. 8/- (Rs. 2/- for Scheduled Castes/Tribes candidates) in the form of crossed Indian Postal Order.

The application form will be supplied on request accompanied by a self addressed stamped envelope of size 23 × 10 cm indicating thereon the name of the post for which the form is required.

Candidates already in service must apply through proper channel. Advance copies of application will not be entertained.

Canvassing in any form and/or bringing in any influence political or otherwise, will be treated as a disqualification.

INTERIM ENQUIRIES WILL NOT BE ATTENDED TO

DRUG INDUSTRY

General News

Drug output in 1979-80 increased appreciably

According to the annual report of the Department of Chemicals and Fertilizers of the Ministry of Petroleum, Chemicals and Fertilizers, the indigenous production of drugs has shown a marked increase during 1979-80. Bulk drugs worth Rs. 220 crore and formulations worth Rs. 1150 crore have been produced this year compared to Rs. 200 crore and Rs. 1050 crore respectively, for 1978-79.

Production of essential drugs showed an overall growth. Increased production was achieved for antibiotics (penicillin, tetracycline, oxytetracycline, and ampicillin), sulpha drugs (sulphamidine, sulphacetamide, sulphaphenazole, and sulphasomidine), vitamins (vitamin B_1 and B_2), analgin, amodiaquin, antidysentery drugs (metronidazole, halogenated oxyguinadine and intestopan), insulin, chlopropamide and caffeine. Doxycycline and Gentamycin were produced for the first time in the country. The report further says that the production of drugs during the year would have been still higher but for the severe constraints of power and shortage of raw materials like caustic soda, lye, dextrose and scarcity of packaging material.

Policy governing foreign drug MNCs

The Union Minister of Petroleum and Chemicals informed Lok Sabha that the role of foreign drug companies had been clearly defined in the new drug policy and there is no question of foreign drug companies obstructing the Indian companies. The Minister denied that his ministry had recommended to the Reserve Bank of India that the foreign drug companies should be treated as high technology companies and allowed to retain their equity shares. According to him, a committee had processed the technology of 207 companies and found that 93 of them were, in fact, using high technology.

In reply to another question he said that the various associations of drug industry have demanded interim price relief owing to the hike in prices of petroleum based products and other raw materials. But the ministry had not yet taken any decision. The price revision would be possible only after finalisation of the relevant procedures and this would take some time.

Certain drug formulations may be decontrolled

A cabinet sub-committee headed by Mr. R. Venkataraman, Union Finance Minister, is examining certain proposals submitted by Bureau of Industrial Costs and Prices under which a new drug policy may come up. The proposals envisage a partial decontrol of drugs, standardisation of formulations and abolition of more brand names. The sub-committee is also examining the recommendations made by BICP to decrease or increase the prices of certain selected drugs (*see* This bulletin, 3, No. 7, p. 218). BICP had found it difficult to work out the price revision of each and every formulation as the number of formula tions is over 15,000. It has recommended decontrol of a number of drugs, retaining control over important essential and other drugs.

The proposed introduction of generic names has been influenced by the success of Italy in abolishing brand names. Standardisation of drug formulation and packagings etc. is already a fairly well established practice in certain western countries. Introduction of these in India would help in bringing down the number of formulations and then it would be easier for BICP to fix prices of standardised formulations.

Rupees 45.13 crore for public sector drug units

A provision has been made in this year's budget for making available Rs. 45.13 crore for public sector drug units : Rs. 4.1 crore will go in the form of capital investment and Rs. 41.02 crore will be in the form of loans. IDPL, HAL, Smith Stanistreet, Bengal Chemicals and Pharmaceuticals Works Ltd., and Bengal Immunity will be benefited by this. The last three companies are the sick units to be taken or already taken over by the Government.

Multinationals plead for price rise

Representatives of the multinational drug firms have told Mr. Veerendra Patil, Petroleum and Chemicals' Minister, that they would be forced to close down their business in India if the prices of drugs are not increased to a remunerative level.

Mr. Patil told the representatives that Government can not sustain its drugs and pharmaceutical activities without the co-operation of the major drug multinationals at the present stage of development. The question of raising drug prices has already been referred to Bureau of Industrial Costs and Prices for detailed examination. However, Government has to see that prices of essential drugs do not go up and their availability poses no problem. Prices of other drugs will be raised suitably.

Brand drugs on the way out

Systematically the Union Government has been able to curb the not much liked activities of the multinationals. The Government has in the first place abolished brand names of 5 drugs, provided for printing of generic names more prominently over brand names and decided not to allow any single ingredient drug introduction under brand names. These decisions followed the recommendations of Hathi Committee report.

These moves seek to curb the excessive expenditure incurred by drug firms in promoting branded drugs. Intensive publicity and high pressure sales compaigns din into the public minds the brand names so much so that even when the patent on a particular drug expires and equivalents are available the consumer will go for the particular brand only. In US, according to the report of a Senate investigation, brand named products are sold at ten times more rates than their generic equivalents. In US the marketing expenditure has been reported to be three to four times the R & D expenditure. Huge wastage of money occurs in creating brand names which are little different from existing medicines.

In India more than 15,000 formulations are available whereas what we need, according to WHO report, are just 200 drugs. Many countries with advanced medicare system—like Sweden and Norway have only 2000 drug formulations.

The drug industry has opposed the Government move saying that introduction of generic drug will (1) bring into market inferior quality drugs from small manufactures; (2) flood the market with drugs having 'bioavailability' problems; (3) confuse the doctors with the long tongue twisting generic names of drugs; and that (4) generic names will also be introduced under manufacturer's name obviously giving him a big advantage and thus nullifying the Government's move.

Hathi Committee has dealt with these posers by saying that even branded products can be of dubious quality. A strict quality control has to be applied in each case. About 'bioavailability' it says that it is not a major problem, even in US and UK taken together there are only 70 such drugs which may cause some problem. About long and confusing names, the Hathi Committee clearly says that once one is used to the system there will be no problem.

The Government can achieve its purpose of debranding all drugs if a periodic review of progress is made of the five drugs already debranded. The Government's ultimate aim of making available drugs to all its citizen can be achieved if drugs are cheaper and a few. This can be done by weeding out irrational combinations, restricting number of formulations for a particular therapeutic category, and making available bulk drugs at a reasonable rate to the small manufactures by bulk purchasing of drugs and then distributing it amongst them.

Industry resents vltamin C distribution policy

The Government's reimposition of control to distribute vitamin C through Chemicals and Pharmaceuticals Corporation has been resented by the drug industry as this has led to a booming black-market for this vitamin.

The new distribution control policy envisages that CPC will make allocations on three producers of vitamin C, namely Jayant Vitamins, Sarabhai Chemicals and Hindustan Antibiotics Ltd. in the proportion of 55,40 and 5 per cent respectively. Under this new policy the actual user has to register its demand with CPC and obtain an authorization slip from it for collection of the supply from the producers, a very time consuming and cumbersome procedure. Because of the reported strained relations between the first two companies, the product which otherwise would have been available has gone underground and the manufacturers are allegedly charging Rs. 150-160 per kg.

Before the introduction of canalising arrangements, vitamin C was available for Rs. 120/ kg against a now controlled price of Rs. 121/kg. This could have been brought down further according to formulators, had the Government allowed the two companies to compete in the open market.

The formulators point out that since the production of this material is large enough to meet the requirements of any number of formulators, this time consuming and costly canalising process should be done away with.

NEWS IN BRIEF

● No sales tax on life saving drugs in Punjab

Dr. Kewal Krishan, Minister of Finance, Punjab while presenting the State budget for the year 1980-81 announced the exemption of life saving drugs from sales tax.

● A rare blood group

An extremely rare blood group called "O-Bombay" has been discovered by a team of Spanish doctors. The group is reported to be found in not more than 30 persons throughout the world.

● Anti-cancer drug extraction technique developed

National Chemical Laboratory, Poona has perfected a technique for the isolation of an anti-cancer agent from *Vinca rosea*, an indigenous perennial herb. The drug, vinblastine sulphate, has appreciable anti-cancer properties and is expected to cost Rs. 2000/gm.

● Improved cancer detection technique

Using a sophisticated CT scanner, manufactured by Pfizer, the scientists of Johns Hopkins Medical Centre have devised a technique by which they can differentiate between benign and malignant lung tumors without surgery (*PMA Newsletters*, **22**, No, 28, 14 July 80).

● Interferon to be produced from foreskins

Weizmann Institute of Science, Rehovot, Israel is building up a plant for the manufacture of interferon using the foreskins of 8 day old babies. The foreskin obtained after circumcision is to be used as the basic human cell tissue for production of interferon.

● Plea to reduce prices of essential drugs

Dr. Ranan Sen, a member of the Hathi Committee, while addressing a convention on "Drug price and its availability" organised by the Patna branch of the Indian Medical Association, called upon the Union Government to reduce the prices of essential drugs and implement the Hathi Committee report forthwith. He said that essential drugs should be made available to the people at cheaperrates.

● Mexico grants drug price rise

The Mexican Health Ministry has allowed three per cent general increase in drug prices (*ABPI News*, No. **179, 5** March 80).

Drugs price revision expected soon

The Government is understood to be favourably considering the long standing demand of drug industry for a price hike of drug formulations. Due to sharp increase in the price of various raw materials, drug units are finding it difficult to operate at a profitable level. As per DPCO 1979 the 'Leader Prices' of drugs in categories I and II were made known. But the Government had not yet forced the industry to bring down the prices to Leader price level.

Now with the possibility of an upward revision of essential drug prices the anticipated fall in the prices of categories I and II may not occur. A new drug price control may come into force to make available life saving drugs at cheaper rates.

Cabinet sub-committee's dilemma over drug prices

The application of mark-ups for different categories of drugs, as recommended by Bureau of Industrial Costs and Prices, has put the Cabinet Sub-Committee on Pharmaceuticals in a dilemma. The implementation will mean that Indian Drugs & Pharmaceuticals Ltd. will entail huge losses as it primarily produces essential bulk drugs, most of which fall in the categories I or II.

The sub-committee which aims to rescue IDPL from its present state of huge losses, can do this only by granting price increase for bulk drugs. This will mean an escalation in cost of formulations thus pushing up the general prices of pharmaceuticals.

The Government is now holding talks with industry representatives for speedy implementation of new mark-ups. The industry has informed the Government that in case new mark-ups are implemented *in toto*, industry will have no option but to go for optimum pattern of production to bring down losses, thus further aggravating the basic drug shortage

The Government is considering a suggestion to freeze prices of categories I and II and allow the prices of categories III and IV to float so that they find their own level but this will be permitted only on the understanding that the industry would meet the country's needs of basic drugs in full.

Bulk drugs production proposals

According to Mr. Veerendra Patil, the following proposals have been received from pharmaceutical companies since the beginning of April, 1980 for the manufacture of bulk drugs.

Company	*Bulk Drug*	*Capacity*
Albert David	Acriflavine	12 tonnes
	Calcium lactopionate	6 ,,
	Iron choline citrate	6 ,,
	Tinidazole	10 ,,
	Tolbutamide	10 ,,
	Chlorpropamide	20 ,,
	Thiacetazone	12 ,,
	Isoniazid	20 ,,

E. Merck	Allergan extracts	600	litres
Glaxo Labs	Chlorpheniramine maleate	1935	kg
	Dequalinium chloride	100	,,
	Diphenoxylate hydrochloride	570	,,
	Furazolidone	6585	,,
	Ibuprofen	17400	,,
	Levamisole	1380	,,
	Norethisterone	270	,,
	Pentazocaine hydrochloride/lactate	1375	,,
	Sotalol hydrochloride	2325	,,
Kothari Plantation & Industries	Chloramphenicol+derivatives	40	tonnes
NVP Menon	Brompheniramine maleate	100	,,
	Cetyl pyridinum chloride	170	,,
	Chlorpheniramine maleate	90	,,
	Glyceryl guaiacol ether	120	,,
	Methocarbamol	85	,,
	Metoclopramide	45	,,
	Pheniramine maleate	85	,,
Pfizer	Cephalexin	38	tonnes
	Cephaloridine	2	,,
	Rifampicin	30	,,
Roche	Ornidazole	15	,,
	Tiberal tablets	16	million
Sudha Drugs & Chemicals	Chloroquin salts	20	tonnes
Unique Chemicals	2-Methylimidazole	300	,,

According to the Minister, a sizeable future investment is expected in the drug industry. The Planning Commission's working group on drugs and pharmaceuticals has envisaged an additional investment of Rs. 370 crore during 1978-79 to 1981-33 for meeting the estimated needs of bulk drugs.

Dicrysticin-8 tops the parenteral drug list

Dicrysticin-S, a penicillin-streptomycin combination of Sarabhai Chemicals is heading the list of parenteral drugs as on the end of February 1980, according to Dr. Y. K. Hamied, Chairman of CIPLA Laboratory. Dr. Hamied was delivering the introductory lecture at IDMA, R&D Seminar on "Parenteral Production —Perspectives, practices and problems". Out of a total retail pharmaceutical market of Rs. 571.5 crore parenteral products' share was Rs. 63.5 crore. Among the therapeutic categories, antibiotics occupied the top place and the position of different therapeutic categories saleswise was as given below:—

Therapeutic Group	*Value in Rs. lakhs*
Antibiotics	2468
Penicillin streptomycin combinations	737
Penicillins	488
Streptomycins	443
Tetracyclines	340
Ampicillins	178
Other antibiotics	282
Vitamins	971
Vitamin B_1, B_6 and B_{12}	627
Vitamin B complex	204
Other vitamins	140
Anabolic hormones including vitamin combinations	400
Sex hormones	366
Progestogens	139
Androgens	118
Other sex hormones	109
Systemic corticosteroids	277
Haematinics	267
Liver extract and combinations	156
Iron and iron combinations	111
Plasma substitutes and *iv* infusions	266
iv Infusions	159
Plasma substitutes	107
Insulin	228
Calcium	198
Antispasmodic anticholinergic	108
Antirheumatic	100
All other therapeutic groups	790
Total parenteral market	6349

Among the parenteral products Dicrysticin-S had a sales of Rs. 3.96 crore during the period March 1979 to February 1980. The first twenty products, according to Dr. Hamied were as follows :—

Rank	*Product*	*Company*	*Value (in Rs. lakhs)*
I	Dicrysticin-S	Sarabhai Chemicals	396
II	Ambistryn-S	Sarabhai Chemicals	365
III	Insulin	Boots	228
IV	Neurobion	E. Merck	205
V	Penidure	Wyeth	170
VI	Terramycin *im*	Pfizer	169
VII	Bistrepen	Alembic	164
VIII	Procaine Penicillin Forte	Alembic	142
IX	Proluton	German Remedies	133
X	Macalvit	Sandoz	121
XI	Omnamycin	Hoechst	120
XII	Durabolin	Organon	120
XIII	Garamycin	C. B. Fulford	103
XIV	Imferon	Ralli-Fison	93
XV	Benzyl Penicillin	Alembic	93
XVI	Decadron	MSD	85
XVII	Trinergic	Unichem	78
XVIII	Triredisol-H	MSD	78
XIX	Betnesol	Glaxo	76
XX	Baralgan	Hoechst	76

Two drug complexes for Tamil Nadu

Tamil Nadu Government has decided to set up two pharmaceutical complexes, one exclusively for the manufacture of formulation and the other for basic chemicals.

The formulation complex is reserved for small scale sector and will be located near Madras. This 100 acre complex is expected to accommodate 50 formulation units. The basic chemicals complex will be located either at Neyveli or Ranipet.

The State Industries Promotion Corporation of Tamil Nadu and Tamil Nadu Pharmaceuticals Manufacturers' Association are jointly promoting the development of these complexes.

Iran a potential buyer of Indian drugs

A delegation of CHEMEXIL which recently visited Iran has come back with hopes of exporting to Iran drugs worth Rs. 10 crore per annum. According to one of the delegates, Iran consumes drugs worth about Rs. 200 crore per annum most of which come from western countries. India can easily export drugs of substantial value if properly organised thrust is made in Iranian market.

Redesigning of drug labels

According to Mr. N. R. Laskar, Union Minister of State for Health, the Government is examining representations from the medical profession on the question of printing generic names more prominently than brand names. The drug industry has represented against the Government move of printing or writing the proper name of a drug in a more conspicuous manner than the trade name.

Drug price muddle

Union Finance Minister, in his budget proposals, had abolished excise duty of 2.5 per cent from 30 selected life saving drugs and levied a special excise duty of five per cent of the basic duty on patent and proprietary medicines. These proposals are reported to have lead to confusion in the prices of drugs, that is the same drug in the market is now available under two different prices. In case of specified 30 life saving drugs new packs are cheaper than the old stock of these medicines as that can not have the advantage of duty exemption.

On the contrary, patent and proprietary medicines' old packs are cheaper than the new ones. All this has put the buyer in a confusion.

According to industry sources the duty exemption for life saving drugs is very insignificant. A pack costing Rs. 10 will become cheaper by only 25 paise. An appreciable reduction can only be made if State Governments and other local bodies remove all levies on life saving drugs.

A consumer is unlikely to get any benefit of the abolition of duty as he will have to pay enhanced rates for patent proprietary drugs.

The manufacturers are sore that both these exercises will cost them substantially in recalculating prices, fresh printing or over-printing of labels etc.

Bulk drugs: Their demand, supply and price structure

In a series of articles in *Financial Express*, Mr. Prafullachandra Bindwai has analysed demand and supply patterns, production snags as well as the price structure of bulk drugs.

According to him, the present shortage of bulk drugs is because of inadequate imports and cutbacks in output by local manufacturers owing to scarcity and rising prices of inputs. The drugs currently scarce are certain antibiotics such as, chloramphenicol and its salts, streptomycin, tetracycline, erythromycin stearate and griseofulvin; penicillins and their derivatives such as ampicillin trihydrate; sulpha drugs like sulphadimidine, phthalyl sulphathiazole, sulphaguanidine and sulphamethoxazole; anti-leprotic DDS; anti-tubercular PAS and INH and some corticosteroids.

This shortage of bulk drugs has led to scarcity of many formulations. The gap between the supply of bulk drugs and their requirements as estimated in 1978 by a working group of Planning Commission is 30-50 percent in cases of INH, some antibiotics and sulpha drugs. In 1979-80 against a demand of 285 tonnes less than 120 tonnes were available in case of chloramphenicol. Similarly the shortfall was quite high in case of the following products, *viz.*, phthalyl sulphathiazole (65.3%), sulphadimidine (31.8%), sulphaguanidine (44.5%), tetracycline (44%) and DDS (36%).

Mr. Bindwai writes that Chemicals and Pharmaceutical Corporation, a State Trading Corporation subsidiary, has not been able to maintain its supply schedule because of insufficient imports. It being the only canalising agency the estimates of the Planning Commission working group have not been fulfilled. The decline in the home production and slashing of imports because of high world market prices of bulk drugs are the reasons contributing to the present shortage.

CPC maintains that even though there was a 10-20 per cent rise in the prices of a wide range of bulk drugs still they have fulfilled the import plan given to them by the working group of Planning Commission, except for two or three drugs. CPC subsidises certain drugs to the extent of 25 per cent or more, e.g. for chloramphenicol supplies it is suffering a loss of Rs. 150-200/kg.

Mr. Bindwai says that the main drawback in the import plan is that it is finalized by planning committee of the Ministry of Petroleum and Chemicals, with the Drug Controller on it without the involvement of CPC or Planning Commission or industry representatives.

In 1979-80, India spent about Rs. 95 crores on the import of bulk drugs, drug intermediates, solvents and other chemicals. During 1980-81 and 1981-82, the imports are bound to cost more, judging by the current prices. The home production has gone down due to several factors such as scarcity of raw materials, power shortage and labour unrest. During 1979-80 the output was alarmingly low like the production of penicillin was 17 per cent below target and streptomycin 11 percent. For phthalyl sulphathiazole the shortfall was 60 per cent. The output of bulk analgesics, antipyretics, anti-histaminics, anti-diarrhoeals, anti-tuberculars and others was 20-70 per cent below target. Though the situation has improved a little in the past six months, it still does not give any hope of reasonable rise in production.

Commenting on the issue of granting price revision, Mr. Bindwai says that the prices of raw materials and excipients have risen between 30 and 135 per cent, particularly the prices of petroleum based products. But so far, Government has not given any relief to industry to offset increase in raw material prices. The prices are governed by DPCO-1979. Since output prices are stagnant, the bulk drug manufacturers are cutting down the production level on one pretext or the other. The OPPI member companies are the main culprits in this. The value of bulk drugs produced by small scale and Indian sectors have increased by 100 and 170 per cent respectively.

Mr. Bindwai concludes that the industry is now all set to demand a price revision under DPCO-79 and its representatives are holding discussions with the Cabinet sub-committee on drugs and pharmaceuticals to convince them of the need to change the drug policy and DPCO-79. It is very certain that unless the Government does not modify its policy, India will continue to suffer from shortages of bulk drugs and formulations.

Iran nationalises foreign drug firms

A Health and Welfare Ministry spokesman of the Revolutionary Council of

Iran has announced that all multinational pharmaceutical factories on its territory have been nationalised. Government managers have been appointed to control these factories.

Drug products get 5% price increase in France

The French Health Minister, Mr. Jacques Barrot, announced a five per cent general price increase for reimbursable pharmaceutical products effective from July 15th, 1980. Under the new system the reimbursement committee will be abolished and manufacturers will be able to submit the application for reimbursement status at the price they choose. This will set a new criterion for reimbursement prices and will lead to abolition of price control. Free and permanent modulation for the reimbursable products also forms the main points of the French Government policy.

Scrip, No. **503,** 4 (7 July 80)

Spain grants 10% increase in drug prices

A 10% price increase has been granted for all pharmaceutical products by Spanish Government. The price increase is automatic and the price of each product will increase by 10%. The industry had pleaded for a 15% increase and is naturally disappointed at such a low level of increase.

Scrip, No. **507,** 3 (21 July 80)

ABPI plea for changes in proposed CTE scheme

The Association of British Pharmaceutical Industry has pleaded to UK authorities to incorporate a number of changes in proposed scheme for exempting manufacturers from Certification of Clinical Trials (CTE). The APBI has put forward the following points:

(1) The proposed scheme should cover all new chemical entities, reformulations, new indications and new doses, i.e., its scope should be the same as that of present CTC;

(2) The industry will provide data summaries to the licensing authorities in support of CTE and fully analysed data could be provided on request;

(3) The CTE application of a company must be accepted as a corporate body application;

(4) The 35-day waiting period between the submission of a CTE application and the start of the clinical trial should be clearly specified;

(5) The ethical committees play an important role but in the proposed scheme they have been given an increased burden which could lead to considerable delays;

(6) The licensing authorities as and when they decide to withdraw a CTE, should give full reasons for doing so; and

(7) The ABPI would like the CTE scheme to run parallel to the present CTC so that products under development could benefit from the new scheme.

Scrip, No. **503,** 2 (7 July 80)

UK pharmaceuticals sales in 1979 increase by 6.4%

According to the figures released by Department of Trade and Industry UK, the sale of pharmaceutical preparations, foods/additives and chemicals reached £1,630 million during 1979, an increase of 6.4%. Sales of pharmaceuticals alone increased by 8.4% to £1,351 million; sales of pharmaceutical foods/additives was £45.7 million (12.5% increase). Among the preparations, the one for the muscular and skeletal systems showed the largest percentage increase, 35.2%. Total exports of pharmaceutical preparations and chemicals fell by 3.1% from £617.3 million to £597.9 mlllion, while the imports went up by 8.5% from £230.3 million to £249.9 million.

Scrip, No. **502,** 4 (2 July 80)

New science prize from 1981

The Holger and Ana-Greta—Crafoored Foundation of Sweden has announced the creation of a new scientific prize to be awarded annually to Swedish or non-Swedish scientists working in the fields of mathematics and astronomy, geoscience or bio-science. The prize expected to be awarded from 1981, carries a cash prize of about 4 lakh kronor ($97,000). The foundation has donated a principal sum of 6 million kronor to Swedish Academy of Science which will award the cash prize out of the interest earned over this amount.

African countries plan Joint drug purchasing

The Commonwealth Regional Secretariat catering to the needs of East, Central and South African countries of Botswana, Kenya, Lesotho, Malawi, Mauritius, Seychelles, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe has formulated a plan for joint purchasing of drugs for these countries. An inter-governmental panel, including the chief pharmacist from each of these 11 countries will discuss the region's drug needs and the ways of meeting these. This system will reduce the cost of drugs substantially.

Scrip, No. **504,** 9 (9 July 80)

$270,000 Million world pharmaceutical market predicted by the year 2000

According to a recently published report, "Opportunities for Pharmaceuticals in the Developing World over the Next Twenty years" by Information Research Ltd., an average 8.5% yearly growth for the next 20 years is expected in the pharmaceutical industry. The estimated worldwide demand will touch $270,000 million compared to 1980 demand of $75,000 million.

Search for new anticancer and antiviral agents will be subjected to more intensified R&D efforts. Broad-spectrum antibiotics will also have to be developed. The anticipated demand for drugs, therapeutic categorywise, will be as given below:

Therapeutic category	*Value in $'000 million* 1980	1990	2000
Analgesics	2.25	4.50	8.10
Antiarthritics	3.75	10.50	24.30
Antibiotics	8.25	18.00	40.50
Cancer chemotherapeutics	1.50	7.50	27.00

Cardiovasculars	6.00	15.00	32.40
Cough & cold prepn	2.25	4.50	5.40
Diuretics	1.50	3.00	5.40
Oestrogens	1.50	4.50	10.80
Psychotics	3.00	9.00	18.90
Steroids	1.50	4.50	10.80
Others	43.50	69.00	86.40
Total	75.00	150.00	270.00

The demand of pharmaceuticals in the LDCs will rise to 25% by the year 2000 from the present 12% to 15% (of the total demand). The estimated demand for different regions of the world will be as follows.

	Value in $ '000 million		
Country	1980	1990	2000
Africa	1.73	7.15	21.22
Asia	17.10	38.46	75.95
E. Europe	12.15	21.76	33.63
Latin America	3.30	11.95	31.70
North America	14.70	23.94	34.60
Oceania	0.67	1.40	2.40
W. Europe	25.35	44.84	70.50
Total	75.00	150.00	270.00

The needs of the developing countries will continue to be for antibiotics, cough and cold preparations, vitamins, analgesics, hormones and tonics. The report also assesses the specific problems and requirements of developing countries and stresses that the greater consumption of drugs is hindered by financial constraints.

As little as 1-2% of GNP is allocated for health care in developing countries compared with 5 to 10% of developed countries. WHO should fund to a considerable extent these health care facilities, the report pleads. The markets of leading 15 developing countries are given below:

	Value in $ million	
Country	1980	2000
Brazil	2270	20,775
Mexico	1240	10,025
Argentina	1890	7,475
Colombia	560	4,755

Venezuela	460	4,410
Egypt	315	3,860
Peru	390	3,745
India	815	3,515
Nigeria	270	3,305
Iran	600	2,660
Indonesia	550	2,435
Algeria	190	2,400
Central America	235	2,255
Morocco	135	1,655
Philippines	370	1,640

The report concludes that in the coming two decades the industry is likely to be affected by the changes relating to the following factors: (*a*) Political involvement; (*b*) Socio-economic pressures; and (*c*) Commercial reactions. These changes will have significant and lasting effects on the structure of the industry. The financial strains in the next 20 years will lead to a point where there will be greater control by a smaller number of companies, each specializing in a particular therapeutic area. By the year 2000 the leading 50 concerns will shrink to about 30 with most of them well established in developing countries.

Scrip, No. **509,** 11 (28 July 80)

Company Reports

Glaxo proposes new formulation unit

A new unit for the manufacture of formulations from bulk drugs like ibuprofen, furazolidine, sotalol hydrochloride etc. at Ambad Industrial Area of Nasik is to be set up by Glaxo Laboratories (India) Ltd.

The project, estimated to cost Rs. 3.75 crore, will be financed through internal accruals and Government incentives.

Marked increase in Vicco Labs production expected

Vicco Labs hope to achieve a production figure of Rs. 10 crore this year compared to Rs. 8 crore for the last year, according to its managing director, Mr. G. K. Pendharkar. The company is primarily engaged in the manufacture of herbal toothpaste and medicines. It expects to export goods worth Rs. 15 lakh this year as against Rs. 10 lakh last year. The company has on hand export orders worth $ 5 lakh for 1980-81.

Mr. Pendharkar said that company is trying to popularise its products, especially toothpaste, in several parts of the world as there is a demand for natural products these days. A toothpaste manufacturing plant is planned to be set up in Yugoslavia and talks for another in Malta are under way.

Most new drug introductions of 1979 in Europe

A survey of the World Pharmaceutical Introductions during 1979 has revealed that most of the new ethical products launched were in Europe followed by Latin America. The introductions totalled 2249 compared to 2892 in 1978. Merck & Co. introduced a total of 44 products. The following table gives the data companywise as well as, areawise :—

Company	Europe	Canada & USA	Latin America	Asia/Africa/ Australia
Merck & Co (USA)	21	8	11	4
Hoechst (Germany)	26	1	14	2
CH Boehringer Sohn (Germany)	22	0	15	2
Schering AG (Germany)	22	0	7	7
ER Squibb (USA)	19	5	10	2
Johnson & Johnson (USA)	22	1	2	8
Hoffman-La Roche (Switzerland)	11	2	11	8
Schering Plough (USA)	8	1	14	6
Bayer (Germany)	14	2	8	4
Ciba-Geigy (Switzerland)	14	2	7	5

Antibiotics introductions topped the list with 255 new antibiotic products (278 in 1978). Systemic corticosteroids, vaccines and antidiabetic preparations increased by 92, 58 and 31% respectively compared to 1978. Laxatives had a 46% drop in new introductions.

Scrip, No. **504,** 4 (9 July 80)

Searle's biotechnology plant by 1981 end

GD Searle & Co. Ltd. has announced that its biotechnology plant designed to produce interferon and other biological material will start functioning by 1981 end. The plant, first of its kind in the world, will produce 9600 million units of fibroblast interferon per month by tissue culture methods. If the clinical trials of interferon thus produced are successful, a data base will be build up for comparison with interferon made by recombinant DNA methods.

Scrip, No. **505,** 8 (14 July 80)

Hoffmann-La Roche sales top among drug firms

According to a paper presented by Dr. Robert Aries at the "Aries International Symposium on Competition in Multinational Drugs" held in Paris on June 19th, 1980, Hoffmann-La Roche occupies the top place among 52 multinational drug companies. The estimated sales turnover, R & D expenditure and expenditure on publicity and information of first ten companies is as follows :

Rank	Name (Country)	Sales $ million	Profit %	R&D Exp. ($ million)	Exp. on publicity & information
1.	Hoffmann-La Roche (Switzerland)	3,100	19	400	300
2.	Merck & Co (USA)	2,200	28	170	230
3.	Hoechst (excluding Roussel) (Germany)	2,000	18	160	280
4.	Ciba-Geigy (Switzerland)	1,800	21	150	220
5.	Bayer (including Miles Lab) (Germany)	1,600	16	100	200
6.	American Home Products (including Wyeth & Ayerst) USA	1,500	24	50	150
7.	Sandoz (including Wander) Switzerland	1.400	17	180	200
8.	Bristol-Myers (USA)	1,400	18	90	210
9.	Warner Lambert (USA)	1,300	14	70	220
10.	Pfizer (USA)	1,300	23	100	170

Scrip, No. **506,** 9 (16 July 80)

KabiGen permitted HGH production

The Swedish Government has permitted KabiGen to produce Human Growth Hormone in the company's virus laboratory in Stockholm. The permission is for 10 litre capacity for somatomedin B and human secretin using hybrid-DNA techniques.

Scrip, No. **510,** 7 (July 80)

Research and Development

Multi-drug treatment for leprosy

The Minister of State for Health Mr. N. R. Laskar informed Lok Sabha that multi-drug treatment in combination with Dapsone is being introduced from 1980-81 in high leprosy-endemicity areas. This will help in early conversion of infectious patients into non-infectious ones and achievement of the disease control.

Ritodrine, a drug to treat premature labour

Ritodrine hydrochloride has been found to be a significantally effective drug for treating premature labour. The drug is being marketed as Yutopar in USA. Deaths among neonates of mothers treated with ritodrine were in the 5% range compared to 13% for babies of mothers receiving other forms of treatment. The US Food and Drug Administration which has monitored this data has, however, cautioned that less than 20 weeks pregnant women should avoid its use. Side-effects in clinical trials were increased heart rate in mothers and foetus, tremor, nervousness and slight fall in BP.

Scrip, No **502**, 11 (2 July 80)

Netilmicin, a new drug for urinary infections

A new drug aminoglycoside netilmicin (Sch 20569; Schering-Plough) has been found to completely cure severe or complicated urinary tract infections. The infections responding to the drug were caused by *E. coli*, *Klebsiella* sp., *Staphylococcus epidermidis*, or *Proteus mirabilis*. No significant side effects were noticed and no ototoxicity was detected. The patient suffering from *Pseudomonas aeruginosa* did not respond to treatment.

Inpharma No. **245,** 8 (12 July 80)

Cisplatin: An important anticancer drug

According to a review published in *Drugs of Today* (*16:5*, 169, 1980) a platinum salt, Cisplatin, has come out to be the most important of the new drugs being used in the cancer chemotherapy during the last five years. Cisplatin (Bristol-Myer) given alone can induce complete or significant regression of various types of cancer such as testicular, lung, stomach, ovarian, uterine or cervical cancers, and all the epidermoid carcinomas, whatever be their origin.

Ketazolam a better anxiolytic than diazepam

In a multicenter study conducted on about 800 patients, although, ketazolam and diazepam were found to be equally effective, ketazolam had fewer side effects compared to diazepam and placebo. Ketazolam also produced less drowsiness than diazepam. The mean doses taken were ketazolam 46 mg and diazepam 25 mg. The study suggests that ketazolam is better than diazepam in treating moderate and severe anxiety as its daily dose produces less side effects and drowsiness than diazepam.

Inpharma, No. **247,** 12 (26 July 80)

New non-steroidal anti-fertility agents

A new series of non-steroidal anti-fertility agents with post coital, post-implantation activity but without hormonal or anti-hormonal activity have been reported by the researchers at Dow's Lepetit Research Laboratories. Of the series, DL-204-IT [2-(3-ethoxy-phenyl)-5, 6-dihydro-s-triazole (5, 1-a) isoquinoline] was selected for further development. It terminated pregnancy in rat, hamster, rabbit, dog, rhesus monkey and baboon when administered *sc* or *im* in single or multiple non-toxic doses. The effectiveness was found to be dependent on the time of gestation, dose and vehicle.

Scrip, No. **506,** 15 (16 July 80)

Adjuvant chemotherapy for breast cancer patients

Pre-menopausal patients with histological evidence of lymph node metastasis and who have undergone mastectomy have been recommended adjuvant chemotherapy. Combinations and full dosage, rather than single drug and lower dosage seem to be more effective.

PMA Newsletter, **22,** No. 29 (21 July 80)

Controlled clinical trials for leprosy vaccine soon

Laboratory for Leprosy and Mycobacterial Research of the National, Institute of Medical Research, UK, may shortly evaluate a leprosy vaccine based on a preparation of *Mycobacterium leprae* derived from infected armadillos and killed by gamma radiation

The controlled clinical and other trials may take almost ten years to judge the real efficacy of the vaccine. If the vaccine is found successful large scale production will be taken up.

Scrip, No. **508,** 11 (23 July 80)

Hepatic failure suspected with sodium valproate treatment

The Medicines Commission of the West German medical association has warned physicians of the possibility of acute hepatic failure in treatment with sodium valproate. Doctors should check hepatic function, including fibrinogen levels before and during the treatment. Where there is a tendency to haemorrhage, thrombocyte count, function and bleeding time should be determined before and during the treatment.

Scrip, No. **510,** 3 (30 July 80)

Of peptide hormone's role in fertility

Scientists attending the American Chemical Society Meeting at Houston were divided over the role of peptide hormone analogs as pro-and anti-fertility agents of the future. Andrew B. Schally of Veterans Administration Medical Centre in New Orleans and Roger Guilleman of Salk Institute in San Diego, who co-shared Nobel Prize in Medicine in 1977, were of different opinions about these peptide hormone analogs. Schally believed that because the analogs are antagonists of leutinizing hormone releasing hormones (LHRH) so they may be potential contraceptives. The Salk group is baffled over the "paradoxical effects" of analogs known as super agonists. These compounds have nominally higher than normal LHRH activity and expected to promote fertility but pardoxically act to prevent it.

Progress in understanding action of these compounds has been slow. Effects in rat, mice and even monkeys often differ from those in humans. About 1000 analogs have been reported so far. Though several super agonists are now available only a few antagonists can be considered 'super'. Hence, clinical efforts in the US have focussed more on agonists. However, one can not predict whether LHRH agonists or antagonists have any future in clinical use.

Chemical & Engineering News, No. **58,** 5 (31 March 80)

Interferon efficacy questioned

Conflicting results have been reported about the efficacy of interferon when used for the treatment of respiratory diseases and certain viral infections. In respiratory diseases what role does it play is not clear. Persons suffering from rhinovirus were given human leucocyte interferon (14×10^7 U total) as nasal sprays for 4 days which significantly reduced symptoms and virus shedding was observed on the second day of the treatment. Less potent material proved ineffective. A method for applying interferon that can ensure prolonged contact with nasal mucosa and knowledge as to how late exogenous interferon may be given in acute respiratory infection so that it remains clinically effective are needed. In viral diseases of the eyes topical interferon at low concentrations does not seem to be an efficient treatment.

Eye drops containing concentrated human leucocyte interferon ($11\text{-}31 \times 10^6$ U/ml) have proved effective in herpetic dendritis. In herpes zoster some benefits such as less persistent pain, inhibition of fresh vesicle formation have been observed with *im* human leucocyte interferon. Similarly chronic viral infections with rubella, cytomegalovirus, herpes simplex or hepatitis B virus were checked but hepatitis B patients had only temporary relief.

Larger doses of interferon have not yet been used because of short supply and dose related toxicity. The major unwanted effects seem to be bone marrow suppression, growth inhibition in young children and temporary loss of hair. Mild side-effects include fever, headache, myalgia and malaise.

Inpharma, No. **246**, 16 (19 July 80)

Vitamin A, iron deficiencies may lead to gastric ulcers

Vitamin A deficiency can lead to gastric ulceration, according to a study reported at the American Chemical Society meeting in Houston by Dr. Eli Seifter of the Albert Einstein College of Medicine, New York.

Studies carried out with rodents point out that they become especially susceptible to toxins including alkylating agents when deficient in vitamin A. Exposure to such toxic chemical represents a kind of stress, the study reports, and the body's response is to shift to muscles the blood from organs such as the stomach and skin. Vitamin A can cancel such responses.

Vitamin A intake can restore some of the damage caused by external stress and its safe intake range is about 10-fold higher than the current recommended daily dose.

In another study presented at the meeting, Dr. S. A. Broitman working at the Boston City Hospital pointed out that dietary deficiency of iron with physical stress leads to gastric ulceration in man. Iron deficiency in the diet can lead to increased proliferation of cells lining the stomach and this may induce some metabolic changes to occur leading to stomach cancer. He has recommended more dietary iron intake.

Chemical & Engineering News, No. **56**, 4 (31 March 80)

Expectorants and antitussives: How much they help?

Role of cough expectorants and suppressants is always debated as cough is often caused by self limiting diseases and it is a common occurrence during viral illnesses.

Expectorants are administered to improve mucokinesis usually by thinning hyperviscous mucus. Water inhalations as mist or steam for patients suffering from cystic fibrosis is usually recommended but long term studies have not confirmed any benefit. Water aerosols in asthma or bronchitis also make lung function worse. Hypertonic electrolyte solutions like ammonium carbonate and chloride though still being used in cough preparations, have a doubtful efficacy. Iodides and organic iodine compounds are the most effective of the mucolytic and mucokinetic agents. However, chronic use may induce side-effects. Studies with Guafenesin (glyceryl guaiacolate), bromhexine, acetylcysteine and proteolytic enzymes show relief in cough but either side-effects or limited benefits are obtained.

Cough suppressants need a judicious use as cough reflex is a protective mechanism which should not be suppressed in most patients. However, these drugs are needed to allow sleep at night, as in whooping cough or in intractable cough in carcinoma of the lung. Codeine is mostly used although pholcodeine has a stronger cough suppressant action. Methadone and diacetylmorphine are excellent cough suppressors but may cause addiction and central depression. Dextromethorphan has no analgesic or addictive property and rarely causes drowsiness and gastrointestinal disturbances. Antihistamines cause much drowsiness and drug secretion though they are effective antitussives.

Inpharma, No. **247**, 2 (26 July 80)

REGULATORY NEWS

New Industrial Policy aims all round growth

The new Industrial Policy announced by Dr. Charanjit Chanana conforms to the Industrial Policy Resolution of 1956. The policy seeks to regularise excess industrial capacity, provide for an automatic growth of five per cent per annum for all industries included in Appendix I of the Industrial Act and promotion of hundred per cent export oriented industries.

The policy which aims an all round growth for industrial sector has redefined small industries in terms of their investment limit which has been raised to Rs. 20 lakh from Rs. 10 lakh. In case of ancillaries the limit has been raised from Rs. 15 to 25 lakhs and for tiny units from Rs. 1 to 2 lakhs.

Useless drug formulations may be delicenced

The Central Drug Control Administration is planning to screen all drug formulations so as to weed out therapeutically unjustifiable and harmful ones among them. At present about 15,000 drug formulations by about 5000 drug units are being marketed; in fact such a large number of formulations are not needed in India. The expert committee appointed by the Government has already submitted a report as to how to rationalize the production of drug formulations. It has also suggested the State Drug Controllers to exercise stricter control over the licensing of formulations as the first measure.

The Government has shown its opposition to certain other practices of drug manufacture, like huge wastage of vitamins as a result of introduction of high-dose vitamin preparations. Now restrictions have been imposed on vitamins that could be added to multivitamin preparations. Although the Drugs and Cosmetics Act are adequate for enforcing quality control measures, most of the states do not use them strictly. As effective controls are not being exercised in issuing licences for drug formulations in most of the states, a plethora of formulations with irrational combinations has resulted.

Benzaldehyde import now under restricted category

A public notice issued by the Chief Controller of Imports & Exports states that import of benzaldehyde has now been transferred from OGL to restricted list. However, the parties already issued irrevocable letters of credit opened through authorised dealers in foreign exchange before the date of this public notice, will be allowed to import this item.

The notice further states that benzaldehyde will not be allowed to be imported by Export-Import firms against additional licences.

Separate drugs control organisation in Tamil Nadu

The present arrangement of Director of Public Health and Preventive Medicine acting as the State Drugs Controller is being discontinued in favour of a separate organisation of drugs control in Tamil Nadu. This is in pursuance of the Hathi Committee recommendations, according to Dr. H. V. Hande, the Tamil Nadu Minister for Health.

Japanese drug 'copy' manufacturers to submit full data

Under an ordinance issued by the Pharmaceutical Affairs Bureau of Japan, the manufacturers of copy drugs which contain new drug ingredient will not be given registration for their products during the period when the original product is in the six year reinvestgation phase. The copy drug manufacturers will have to submit virtually the same amount of information as the originator concern. This will include the results of the full range of toxicity tests (acute, subacute, chronic, fertility, dependence, antigenicity, mutagenicity), full pharmacokinetics, pharmacology and clinical trials.

Scrip, No. **503,** 10, (7 July 80)

PAHO to implement drug control plan

A National Drug Control Plan is being implemented by Venezuela, Colombia and Ecuador the member countries of the Pan American Health Organisation. The plan aims to promote the programmes of technical cooperation, information exchange, uniform standards, and harmonization in the registration, labelling and advertising of drugs, drug devices and cosmetic products. The implementation of this plan which is recommended by WHO will improve the trade relations of these countries with European Economic Community.

International Drug Regulatory Monitor, No. **86,** 1 (July 80)

Benzodiazepine not for 'everyday stress'

Benzodiazepine manufacturers in USA have agreed to include the following statement for the information of physicians, "Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic drug".

The companies agreeing to comply with the requirement are : Hoffmann-La Roche (Librium and Valium); Warner Chilcott (Verstran) ; Abbott (Tranxene and Azene); Wyeth (Serax and Ativan); and Parke-Davis (Centrax).

Scrip, No. **507,** 9 (21 July 80)

Bioequivalence problem in Probenecid

A new US Food and Drug Administration dissolution test has indicated that various brands of probenecid are not having comparable therapeutic effects. According to FDA, there is well documented evidence of actual or potential bioequivalence differences in oral formulations of probenecid among currently marketed brands of the same drug. Significantly poor bioavailability can, when taken with penicillin, lead to inadequate treatment of serious infections such as venereal diseases. Overdoses can lead to CNS stimulation, convulsions and respiratory failures.

Scrip, No. **509**, 9 (28 July 80)

Common Arab health policy mooted

A special meeting of the Council of Arab Health Ministers will be held in March 1981 at Algiers to evolve a common Arab health policy. A working party has already been set up to collect background data for a Pan-Arab strategy for the pharmaceutical industry.

Scrip, No. **510,** 9 (30 July 80)

PRODUCTION/IMPORT FIGURES

ESSENTIAL BULK DRUG PRODUCTION DURING 1979-80

Name of the Bulk Drug	Production during 1979-80
I. *ANTIBIOTICS*	
1. Penicillin	326.96 MMU
2. Streptomycin	220.16 Base T
3. Chloramphenicol powder	74.85 T
4. Tetracycline	141.09 T
5. Oxytetracycline	113.96 T
6. Ampicillin	16.77 T
7. Erythromycin (Estolate/Stearate)	23.05 T
II. *SULPHA DRUGS*	
8. Sulphadimidine	513.44 T
9. Sulphacetamide	38.17 T
10. Sulphaphenazole	104.70 T
11. Sulphasomidine	235.47 T
12. Phthalyl sulphathiazole	6.48 T
III. *VITAMINS*	
13. Vitamin A	58.76 MMU
14. Vitamin B_1	48.76 T
15. Vitamin B_2	7.44 T
16. VitaminB_{12}	126.53 kg
17. Folic acid	3.51 T
18. Vitamin C	760.03 T
IV. *ANALGESICS, ANTIPYRETICS ETC.*	
19. Analgin	346.90 T
20. Aspirin	995.61 T
21. Paracetamol	112.81 T
22. Phenyl butazone	52.93 T
23. Oxyphenyl butazone	23.95 T
24. Codiene & salts	8.38 T

Name of the Bulk Drug		Production during 1979-80
V.	*CORTICOSTEROIDS*	
25.	Prednisolone	1,147.30 kg
26.	Dexamethazone	95.42 ,,
27.	Betamethazone	348.17 ,,
VI.	*ANTI T. B. DRUGS*	
28.	PAS & its salts	481.78 T
29.	I. N. H.	112.43 T
30.	Thiacetazone	12.55 T
VII.	*ANTIMALARIALS*	
31.	Chloroquin	35.16 T
32.	Amodiaquin	38.49 T
33.	Quinine	14.43 T
VIII.	*ANTIDYSENTERY DRUGS*	
34.	Metronidazole	88.85 T
35.	Halogenated oxyquinolines	223.13 T
	(*a*) Di-iodo-hydroxyquinolines	11.57 T
	(*b*) Iodo-chloro-hydroxyquinolines	158.54 T
	(*c*) Intestopan substance	53.02 T
IX.	*ANTIDIABETICS*	
36.	Insulin	1,507.00 MU
37.	Chlorpropamide	11.83 T
38.	Glybenclamide	0.44 T
X.	*C. N. S.STIMULANTS*	
39.	Caffeine	107.65 T
XI.	*DIURETICS*	
40.	Frusemide	4.19 T
XII.	*ANTIASTHAMETICS*	
41.	Ephedrine	29.47 T
XIII.	*CARDIOVASCULAR DRUGS*	
42.	Xanthinol nicotinate	13.38 T
43.	Digoxin	5.79 kg
XIV.	*ANAESTHETICS*	
44.	Lignocaine/Xylocaine	6.77 T

Contd.

Name of the Bulk Drug		Production during 1979-80
XV.	*ANTHELMENTICS*	
45.	Piperazine & its salts	86.72 T
XVI.	*ANTIHISTAMINICS*	
46.	Pheniramine maleate	8.83 T
XVII.	*TRANQUILIZERS & SEDATIVES*	
47.	Phenobarbitone	26 41 T
XVIII.	*ANTIFILARIALS*	
48.	D. E. C. citrate	21.57 T
XIX.	*ANTI LEPROTICS*	
49.	D. D. S. (Dapsone)	16.20 T
XX.	*IMMUNOLOGICAL AGENTS*	
50.	Triple vaccine	7,103.67 Ltrs.

IMPORT STATISTICS OF VARIOUS DRUGS DURING APRIL 1979 TO DECEMBER 1979

Name of the Bulk Drug	Quantity Imported
I. *ANTIBIOTICS*	
1. Chloramphenicol base	35 MT
2. Chloramphenicol palmitate	25 MT
3. Chloramphenicol sodium succinate	3,235 Kg
4. Tetracycline hydrochloride	131.5 MT
5. Doxycyclin hydrochloride	2,071.3 Kg
6. Penicillin G. sodium	17,600 BU
7. Penicillin G. procaine	6,492 BU
8. Ampicillin Trihydrate/anhydrous	43.7 MT
9. Framycetin sulfate	1,870 Kg
10. Neomycin sulfate	4,931 Kg
11. Cephalexin	855 Kg
12. Gentamycin	432 Kg
13. Cycloserine	1,800 Kg
14. Rifampicin	2,877 Kg
15. Bacitracin/Bacitracin zinc	33.1 BU
16. Polymixin	402 BU
II. *SULPHONAMIDES*	
17. Sulphadiazine	139.3 MT
18. Sulphamethoxazol	46.2 MT
III. *VITAMINS*	
19. Vitamin A	28.5 MMU
20. Vitamin B_1	58.6 MT
21. Vitamin B_2	21.1 MT
22. Vitamin B_6	36.8 MT
23. Titamin B_{12}	4.7 Kg
24. Folic acid	307.5 Kg
25. Sodium/Calcium pantothenate	40.5 MT
26. Panthenol	12.6 MT
27. Vitamin C	54.5 MT

Name of the Bulk Drug	Quantity Imported
IV. *ANALGESICS, ANTIPYRESTICS, ANTIRHEUMATICS ETC.*	
28. Analgin	100.7 MT
29. Oxyphenylbutazone	8.4 MT
30. Amidopyrine	71.2 MT
31. Dextroproxyphene	4,880 kg
32. Aspirin	211.2 MT
33. Pyrithyldone	8.0 MT
34. Propoxyphenazone	24.0 MT
V. *CORTICOSTEROIDS*	
35. Prednisolone	742.4 kg
36. Hydrocortisone	295 kg
37. Dexamethasone	141.3 kg
38. Triamcinolone	62.6 kg
VI. *ANTI T. B. DURGS*	
39. Ethambutol	81.7 MT
40. Pyraxinamide	4.1 MT
VII. *ANTIMALARIALS*	
41. Chloroquin & its salts	50.4 MT
VIII. *ANTIDYSENTERY DRUGS*	
42. Furazolidone	26 MT
IX. *DIURETICS*	
43. Aminophylline	25.8 MT
44. Theophylline	64.4 MT
45. 7(2-Hydroxyethyl)theophyline	10.4 MT
X. *ANTIASTHMATICDRUGS*	
46. Salbutamol	301 kg
47. Ephedrine & Salts	13.3 MT
XI. *CARDIOVASCULAR DRUGS*	
48. Methyl dopa	2,893 kg
XII. *ANTHELMINTICS*	
49. Piperazine hexahydrate	90.0 MT
50. Thiabendazole	14.3 MT

Name of the Bulk Drug	Quantity Imported
XIII. *ANTIHISTAMINICS*	
51. Tripolidine	220 kg
52. Chlorpheniramine maleate	14.5 MT
XIV. *TRANQUILIZERS & SEDATIVES*	
53. Thioridazine	2,990 kg
XV. *ANTIEPILEPTICS*	
54. Phenylhdantoin sodium	12.2 MT
XVI. *BLOOD PREPARATIONS:*	
55. Polyvinyl pyrrolidone	31.3 MT
XVII. *FEMALE SEX HARMONES*	
56. Norethisterone	128 kg
57. Lynestrenol	52 kg
XVIII. *OTHERS:*	
58. Trimethoprim	4,208 kg

INDUSTRIAL LICENCES AND LETTERS OF INTENT

Issued During May, 1980

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence, No. and date
	Licences				
1.	Anglo-French Drug Co. (Eastern), 28 Tardeo Road, Bombay.	Bangalore	(*i*) Amylobarbitone sodium (*ii*) Butabarbitol sodium (secbutobarbitone sodium) (*iii*) Phenytoin sodium	2,000 kg (for items *i* and *ii* together) 10,000 kgs	New Article CIL: 130/80 dated: 16.5.80
2.	Lupin Laboratories Pvt. Ltd., 159, C. S. T. Road, Kalina, Santacruz (East), Bombay.	Ankleshwar	(*i*) Ethambutol hydrochloride (*ii*) Trimethoprim	15 tonnes 5 tonnes	New Article CIL: 141/80 dated: 22.5.80
3.	Paushak Ltd., Alembic Road, Baroda.	Baroda	Phenylbutazone (basic drug)	25 tonnes	New Article CIL: 122/80 dated: 6.5.80
4.	Raptakos, Brett & Co. Ltd., 47, Dr. Annie Besant Road, Worli, Bombay.	Roha Distt: Kolaba (Maharashtra)	Calcium lactobionate (bulk drug)	50 tonnes	New Article CIL: 138/80 dated: 22.5.80
5.	Searle (India) Ltd., Ralli House, P. O. Box No. 166, 21, Raveline Street, Bombay.	Ankleshwar	Norpace chemical (diisopyramide phosphate and its formulations)	1,000 kgs	New Article CIL: 142/80 dated: 23.5.80

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence, No. and date
6.	Unichem Laboratories Ltd., S. V. Road, Jogeshwari (W) P. Bag No. 6459, Bombay.	Kolaba	(*i*) Tinidazole (bulk drug)	20 tonnes	New Article CIL: 128/80 dated: 16.5.80
			(*ii*) Tablets of tinidazole	Corresponding to 70% of their own annual production of bulk drug	
7.	Uniloids Ltd., 3-6-525 Himayat Nagar, P. B. No. 1027, Hyderabad.	Hyderabad	I. *Tablets*:		New Article CIL: 125/80 dated: 8.5.80
			1. Normozyme	40,00,000 tablets	
			2. Neo flagivon 200 mg (metronidazole)	*	
			3. Neo flagivon 200 mg	*	
			4. Cortophen	48,00,000 ,,	
			5. Rumipyrine	48,00,000 ,,	
			6. Examide	48,00,000 ,,	
			7. Versalin	48,00,000 ,,	
			8. Depranil	48,00,000 ,,	
			9. Trimethoprim sulphamethoxazole	50,00,000 ,,	
			10. Glybenclamide	60,00,000 ,,	
			11. Tricambin 12 drags	60,00,000 ,	
			12. Calcium uniloids	1,00,00,000 ,,	
			13. Cough tablets	50,00,000 ,,	
			14. Tetracycline	50,00,000 ,,	

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* The capacity of items at Sl. No. 2, 3 and 18 put together will correspond to 7 tonnes of their own production of the bulk drug metronidazole.

Contd.

Sl. No.	Name & Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence, No. and date
			II. *Syrup:*		
			15. Normozyme (100 ml)	2,00,000 ,,	
			16. Cough Linctus (100 ml)	2,00,000 ,,	
			17. Vitaloid syrup (200 ml)	3,00,000 ,,	
			18. Neo flagivon syrup (30 ml and 60 ml)	*	
			III. *Capsules:*		
			19. Becoloids	72,00,000 capsules	
			20. Microsules	72,00,000 ,,	
			21. Vitacycline	12,00,000 ,,	
			IV. *Ointment:*		
			22. Benzoscab 25 gm	6,00,000 tubes	
			23. Injection of heparin	50,000 vials	
	Letters of Intent				
1.	Albert David Ltd., 15, Chittaranjan Avenue, Calcutta.	Ghaziabad (UP)	(15-S)-15 methyl prostaglandin F2 alpha thamprostin 15 M (corboprost tromethamine sterile solution)	5 lakh vials (of 10 ml each)	Substantial, Expansion LI: 188/80 dated: 28.5.80
2.	The Bengal Immunity Co. Ltd., Immunity House, 153, Lenin Saranee, Calcutta.	Calcutta	Formulation of ampicillin in the form of capsules and granules, syrup based on bulk drugs consumption of		New Article LI: 151/80 dated: 9.5.80
			(*i*) Ampicillin anhydrous	2898 kgs	
			(*ii*) Ampicllin trihydrate	252 kgs	

NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
1.	*Antacid*			
	Aluminium hydroxide + magnesium hydroxide + simethicone	Duoqu ll	Wellcome	Australia
2.	*Antiallergic*			
	Cromolyn sodium (Sodium cromoglycate)	Nalcrom	Fisons	Canada
3.	*Antianginal*			
	Nifedipine	Adalat	Bayer	Israel
	Nitroglycerin ointment (glyceryl trinitrate)	Nitro-Bid	Marion	S. Africa
4.	*Antiarrhythmic:*			
	Lorcainide	Lorcainide	Janssen	W. Germany
	Mexiletine	Mexitil	Boehringer Ingelheim	Sweden/ W. Germany/ Australia
5.	*Antiarrhythmic/antianginal*			
	Verapamil	Falicard	Fahlberg-List	E. Germany
6.	*Antibacterial*			
	Azlocillin	Securopen	Bayer	Switzerland
	Cefaclor	Ceclor	Lilly	Hong Kong/ Switzerland
	Cefadroxil	Duracef	Ciba-Geigy	Switzerland
	Cefamandole	Kefandol	Lilly	France
	Cefotaxime	Claforan	Roussel	Italy
	Cefoxitin	Merxin	Nippon Merck	Japan
	Cefsulodin	Monaspor	Ciba-Geigy	Switzerland
	Cephradine	Abisporon	Abic	Israel

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
	Cephradine	Lisacef	Lisapharma	Italy
	Gentamicin+ zirconium dioxide	Septopal	BDH	UK
	Pivmecillinam	Selexid	Leo	Hong Kong/ Switzerland
	Tetroxoprim+sulfadiazine	Sterinor	Heumann	W. Germany
	Trimethoprim	Proloprim	Wellcome	USA
	Trimethoprim	Trimetoprim	Recip	Sweden
	Trimethoprim	Trimopan	Farmos	Sweden
	Trimethoprim	Trimpex	Roche	USA
7.	*Antidepressant*			
	Clomipramine	Neoprex	Trima Unipharm	Israel
	Etoperidone	Staff	Sigma-Tau	Italy
	Maprotiline	Ludiomil	Ciba-Geigy	Israel
	Nomifensine	Alival	Hoechst	Israel
	Nomifensine	Merital	Hoechst	Hong Kong
8.	*Antidiarrhoeal*			
	Loperamide	Imodium	Leo	Sweden
9.	*Antidote*			
	Timonacic	Tiazolidin	UCM-Difme	Italy
	Tiopronin	Thiola	Santen	Japan
10.	*Antifungal*			
	Ciclopirox olamine	Batrafen	Hoechst	Brazil/ S. Korea
	Econazole	Gyno-Pevaryl	Cilag	Israel
	Isoconazole	Travogen	Schering AG	Switzerland
	Miconazole	Florid	Mochida	Japan
11.	*Antihypertensive*			
	Guanfacine	Estulic	Sandoz	Switzerland
	Nitroprusside	Nipruton	Berlin-Chemie	E. Germany
12.	*Antihypertensive/diuretic*			
	Spironolactone + furosemide	Lasilacton	Hoechst	Switzerland

Contd.

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
13.	*Anti-inflammatory*			
	Fenbufen	Cinopal	Lederle	Israel
	Flurbiprofen	Flurofen	Boots	Israel
	Flurbiprofen	Froben	Thomae	W. Germany
	Ibuprofen	Brufen	Boots	E. Germany
	Ibuproxam	Ibudros	Manetti-Roberts	Italy
	Indoprofen	Flosint	Farmitalia	S. Korea
	Ketoprofen	Profenid	Specia	Israel
	Proquazone	Biarison	Sandoz	Hong Kong
	Protizinic acid	Pirocrid	Mochida	Japan
	Suxibuzone	Danilon	Taiho	Japan
14.	*Anti-inflammatory analgesic*			
	Naproxen sodium	Anaprox	Syntex	Canada
15.	*Antineoplastic*			
	Cisplatin	Platinol	Bristol	Canada
	Improsulfan tosilate	Protecton	Yoshitomi	Japan
	Teniposide	Vumon	Bristol	W. Germany
	Vindesine		Lilly	W. Germany
16.	*Antiparkinsonian*			
	Benserazide+levodopa	Dopasol	Kyowa Hakko	Japan
	Benserazide+levodopa	Neodopasol	Daiichi	Japan
17.	*Antiparasitic*			
	Secnidazole	Flagentyl	Rhone-Poulenc	Switzerland
18.	*Antipsychotic*			
	Loxapine	Loxapac	Lederle	France
	Perphenazine enanthate	Cetrane	Schering Plough	France
19.	*Antispasmodic*			
	Oxybutynin	Ditropan	Marion	Hong Kong/ S. Africa
20.	*Antispasticity*			
	Baclofen	Gabalon	Daiichi	Japan

Contd.

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
21.	*Antithrombotic*			
	Urokinase	Abbokinase	Abbott	W. Germany
22.	*β-Blocker*			
	Metoprolol	Seloken	Searle	France
	Penbutolol	Betapressin	Hoechst	W. Germany
	Pindolol	Visken	Sandoz	Israel
	Talinolol	Cordanum	Arzneimmittel-werk-Dresden	E. Germany
23.	*β-Blocker/diuretic*			
	Pindolol+clopamide	Viskaldix	Sandoz	Hong Kong
	Propranolol+bendrofluazide	Inderetic	ICI	Switzerland
24.	*Bronchodilator*			
	Carbuterol	Bronsecur	Smith Kline & French	W. Germany
	Fenspiride	Pneumorel	Servier	Hong Kong
25.	*Calcium regulator*			
	Alfacalcidol (1α-hydroxyvitamin D_3)	One-Alpha	Leo	Hong Kong
26.	*CNS stimulant*			
	Piracetam	Gabacet	Carrion	France
27.	*Corticosteroid/antifungal*			
	Isoconazole+diflucortolone valerate	Travocort	Schering AG	Switzerland
28.	*Debriding agent*			
	Dextranomer	Debrisan	Green Cross	Japan
29.	*Diuretic/antihypertensive*			
	Tienilic acid (ticrynafen)	Selcryn	Smith Kline & French	Argentina
30.	*Glaucoma treatment*			
	Dipivefrin	Propine	Allergan	USA

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
31.	*H_2-Receptor antagonist*			
	Cimetidine	Gastromet	Trima	Israel
	Cimetidine	Tagamet	Smith Kline & French	Malaysia
	Cimetidine	Ulcedine	ICN	Mexico
32.	*Hypoglycemic*			
	Gliquidone	Glurenorm	Boehringer Ingelheim	Hong Kong
33.	*Hypouricemic*			
	Allopurinol	Lopurin	Boots	USA
34.	*Immunopotentiator*			
	Procodazol	Estimulocel	Lafarquim	Spain
35.	*Laxative*			
	Picosulfate sodium	Laxoberon	Teijin	Japan
36.	*Ocular anti-inflammatory/antibacterial*			
	Gentamicin + betamethasone	Garasone	Schering Corp	Hong Kong
37.	*Ocular antiviral*			
	Trifluridine	Viroptic	Wellcome	USA
38.	*Peripheral vasodilator*			
	Cinnarizine	Sturgeon	Cilag	Switzerland
	Suloctidil	Duloctil	Searle	Argentina/ France
39.	*Photosensitizing agent*			
	Methoxsalen	Oxsoralen	Elder	S. Africa
40.	*Pressor agent*			
	Prenalterol	Hyprenan	Hassle	Sweden
41.	*Thrombolytic*			
	Urokinase	Abbokinase	Abbott	France
42.	*Topical corticosteroid*			
	Diflorasone diacetate	Surfone	Upjohn	Hong Kong

Contd.

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
43.	*Tranquilizer*			
	Clorazepate	Mendon	Dainippon	Japan
	Tetrazepam	Clinoxan	Midy	W. Germany
44.	*Uricosuric*			
	Benzbromarone	Uricovac	Labaz	E. Germany
45.	*Vasodilator*			
	Flunarizine	Sibelium	Janssen	Switzerland
	Vincamine	Vincimax	Synthelabo	France

BOOK REVIEWS

Directory of On-going Research in Cancer Epidemiology 1979

Edited by C. S. Muir & G. Wagner, Lyon, International Agency for Research on Cancer, 1979 (IARC Publications No. 28), Pages 672, Price: Sw. fr. 30.

The Directory, contains the abstracts of 1092 on-going, as yet unpublished, research projects in cancer epidemiology from 67 countries. The contents show a continued increasing interest in the health consequences of specific industrial exposures. It also reveals that lung, breast, cervix uteri and gastrointestinal tract cancers are still the sites most commonly studied, while little is being done on other common cancers, such as those of the pancreas, prostate and malignant melanoma. Most of the work is reported from Europe, Japan and North America. However, some studies are reported from developing countries, mostly South America.

The various indexes make it easy to find desired information. There are indexes by term, cancer site, chemical involved, type of study, country where the study is being undertaken, and investigator. A helpful feature is that the full address of the investigator is given with each entry. The Directory also contains a list of population-based cancer registries. □

Oncogenesis and Herpesviruses III, Part 1 and Part 2

Edited by G. de-The, W. Henle & F. Rapp, Lyon, International Agency for Research on Cancer, 1978. Part I: Pages 1-580; Part II: Pages 581-1102 (IARC Scientific Publications No. 24). Price: Part 1: US$ 30.-, Sw. fr. 50.-; Part 2: US$ 30.-, Sw. fr. 50.-. Distributed for IARC by the World Health Organization.

The role of viruses in the causation of cancer in humans has attracted a vast amount of research in the last 10-15 years. Whilst at first the retroviruses (or oncornaviruses) seemed the most promising candidates, nowadays interest in the herpesviruses has been stimulated by the strong evidence of an association between Epstein-Barr herpetovirus and Burkitt's lymphoma.

However, this volume published in two parts-contains papers dealing with some dozen different herpesviruses, for only some of which any claims of oncogenic potential are made.

Most of the papers deal with fundamental aspects of virology—the structure of the viral genome and its interaction with cellular DNA, viral antigens, and the whole range of cell-virus interactions. There are a few papers that deal with the oncogenicity of certain herpesviruses in humans and animals.

Several papers discuss aspects of Marek's disease in chickens and the effectiveness of the vaccines that have been produced against the Marek's disease virus. Not surprisingly, the analogous studies have been considered in relation to the herpesvirus-associated diseases in man—Burkitt's lymphoma and nasopharyngeal cancer—but the preparation of a vaccine against the Epstein-Barr virus continues to present considerable technical problems and, in any case, its application would present considerable ethical and epidemiological difficulties.

Together, the two parts of this volume present completely the current developments in all aspects of herpesvirus-related research. □

International Agency for Research on Cancer: Annual Report 1979

Lyon, 1979, Pages 194, Price: Sw. fr. 80 US$ 8.

The International Agency for Research on Cancer has continued its programme of research directed to establishing risk factors for human cancer.

The Agency is engaged in a series of analytical epidemiological studies, particularly related to the etiology of cancers of the gastrointestinal tract. The role of alcoholic beverages has been extensively studied.

The Agency is collaborating with institutions in Denmark, Norway, Sweden and the United Kingdom investigating the health risks related to exposure to man-made mineral fibres, materials that are being extensively produced and used, often as substitutes for asbestos. The study covers producers and users, especially in the building industry. A related study in Turkey is investigating the endemic occurrence of mesothelioma in certain villages, thought to be related to exposure to a locally occurring mineral fibre.

The identification of carcinogens in the environment demands high-precision analytical techniques. The Agency has itself concentrated on the development of analytical methods for the volatile *N*-nitrosamines and the aflatoxins. Details are given of studies on *N*-nitrosamine formation, as well as analysis of a variety of environmental samples.

Etiological studies of Burkitt's lymphoma and nasopharyngeal carcinoma, two tumours with which the Epstein-Barr herpesvirus is associated, have been pursued. The virus is evidently only one of the causative agents of Burkitt's lymphoma, and a malaria suppression trial, in Mara region, Tanzania, is being carried out, in the hope that with the suppression of malaria, Burkitt's lymphoma incidence will also be diminished.

The identification of carcinogenic chemicals occurring in the environment and the evaluation of their carcinogenic risk to humans have continued as a major activity of the Agency. A total of 456 chemicals have been evaluated in the first 19 volumes of the *IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans*, and for 37 groups of chemicals, or industrial processes, a positive association with human cancer has been found. The development and improvement of short-term carcinogenicity tests, and the investigation into mechanisms of carcinogenesis are reported in detail. Of particular importance are the studies on the "multistage model" of carcinogenesis in animals, including the process of "initiation" and "promotion" of cancer, which are of vital importance in current epidemiological studies of cancer in humans. □

Vitamin A

DR. P. K. Ghosh*

Vitamin A is known to exist in two molecular structures designated as vitamin A_1 and vitamin A_2. Vitamin A_1 known as retinol is an "all-trans" compound. Vitamin A_2 is "3-Dihydroretinol". All the synthetic vitamin A are derivatives of retinol only. As is well known, vitamin A is available in plenty from animal sources; liver being a rich source. Fish liver oils are important natural sources of vitamin A. While fish liver oil obtained from the sea-fish contains vitamin A_1 only, the sweet-water-fish-liver-oil contains both A_1 and A_2. However, pure vitamin A is made by synthetic methods. Deficiency of vitamin A in men and animals is manifested by drynesss in skin, retarded growth in children and night blindness, in general, as the early symptoms which is aggravated to conjunctivitis of the eye and finally to total blindness in severe deficiency. The normal dietary requirements of vitamin A vary with age, and sex and are usually about 2,500 to 3,500 IU for children (below 12 years) and about 4,500 to 5,000 IU for adults.

2. Demand:

Total availability figures computed from the indigenous production and imports into the country show vitamin A having had a compound growth rate of about 12% from 1970-71 to 1979-80. The growth rate has shown an increase during the recent years from 1977-78 onwards. With the normal availability of vitamin A at slightly over 50 MMU during 1977-78, reports of shortage in the country came to surface for the first time after about seven years. On the basis of the appraisal of the situation prevailing during the last 3 years, the demand of vitamin A during 1977-78, 1978-79 and 1979-80 could be placed at 60 MMU, 70 MMU and 80 MMU respectively, although the actual availability was 50.2 MMU, 77.2 MMU and about 96 MMU respectively. In the projection of future demand it is expected, that the following would be the demand of vitamin A during the next 5 years:—

Year	*Quantity in MMU*
1980-81	100
1981-82	115
1982-83	130
1983-84	150
1984-85	170

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3. Supply:

The following is the capacity break-up, approved as on date, for the basic production of vitamin A:

Name of the Company	*Unit*	*Approved Capacity* *IL**	 *LI***	 *Total*
1. Roche Products Ltd, Bombay	MMU	15	—	15
2. Glaxo Laboratories Ltd, Bombay	,,	30	—	30
3. Kerala State Drugs & Pharmaceuticals Ltd, Alleppey	,,	30	—	30
				75

* Industrial Licence; ** Letter of Intent.

The supply of vitamin A through indigenous production during the last 3 years had been as under:

1977-78	50.2 MMU
1978-79	62.2 ,,
1979-80	58.8 ,,

Imports during the same period had been nil, 15 MMU and 37 MMU respectively.

Of the three units, approved for manufacture of the item, only Roche and Glaxo are in production. Kerala unit is expected to come into production by the middle of 1981-82. If everything goes well, the total availability of vitamin A through indigenous production from the two producing units during this year (1980-81) would be of the order of 60-65 MMU. This would leave a gap of about 35-40 MMU which would need to be imported. Next year (1981-82), if Kerala unit comes into production, the indigenous production may reach, at best, a level of 75-80 MMU which would again necessitate imports of substantial quantity of the item. Prediction of the situation beyond 1981-82 would not be much meaningful at this stage.

4. Growth:

Past (1970-71 to 1979-80) average about 12% (compound) per year. Future (1980-81 to 1984-85) expected around 13-15% (compound) per year.

5. Price:

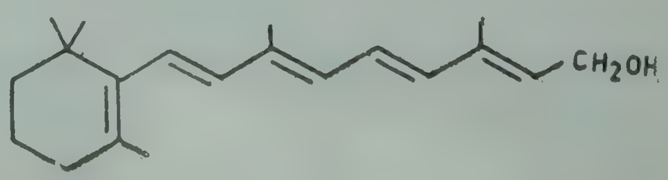
Vitamin A is available commercially in bulk form as retinol acetate and palmitate, diluted in refined vegetable oil with added stabilisers. The price, controlled by the Government, is Rs. 562 00 per 1,000 MIU for both acetate and palmitate. Other commercial forms are: admixed with emulsifiers and stabilisers and packed in dry form which when reconstituted is miscible with water; coated with gelatine and sugar and packed dry and mixed with vitamin D_3 and other viamins like E, C and K etc.

6. Consumption/Use:

Bulk vitamin A is consumed in a major way in the production of various drug formulations; nearly 35 to 40 MMU annually is consumed in the manufacture of various drug formulations representing nearly 65 to 70% of the total availability of vitamin A. Besides a substantial quantity of the order of 14 to 17 MMU (30-35%) goes in for enriching hydrogenated oil in the vanaspati industry as per the statutory requirements.

7. Important production techniques of vitamin A (Retinol):

The following is the accepted structure for retinol:



As this molecule conatains five double bonds it could, therefore, exist in thirty two different geometrically isomeric forms. However, it is the "all-trans" isomer which is desirable, because all the other known isomers have less activity than the "all-trans" isomer. At the moment only six isomers have been isolated of which, only four are naturally occurring ones. The six isomers which have been isolated are:

(*i*) The "All-trans" retinol (activity 100%),

(*ii*) 13-cis-7,9,11-tri-trans-retinol also called Neovitamin Aa (activity 75%)

(*iii*) 9-mono-cis 7,11,13 tri-trans-retinol also called Isovitamin Aa (activity 25%)

(*iv*) 9,13 di-cis-7,11-di-trans-retinol also called Isovitamin Ab (activity 25%)

(*v*) 11-cis 7,9,13-tri-trans-retinol also called Neovitamin Ab (activity 25%)

(*vi*) 11,13-di-cis-7,9-di-trans-retinol also called Neovitamin Ac (activity 25%)

Since the "all-trans" retinol is the desired isomer, great care has to be taken to ensure that only this isomer is formed during the synthesis. As a matter of history it is important to mention that vitamin A was synthesised for the first time by R. Kulin & C. J. R. Morris (*Ber.*, **70,** 853, 1937); the synthesised material had, however, only about 7.5% of the vitamin A activity. Obviously, the material was impure; it could be that it was also contaminated largely with less active isomers.

At present, the industrial methods of synthesis follow the routes, propounded largely by O. Isler *et. al* [(*i*) *Experientia*, **2,** 31, *1946*; (*ii*) *Helv. Chim. Acta*, **30,** 1911 *1947*; (*iii*) *Helv. Chim. Acta..*, **32,** 489, *1949*; (*iv*) *Chimia* (*Aarau*), **4,** 103 *1950*], wherein an aldehyde, commonly known as "C_{14}-aldehyde", is initially synthesised using betaionone as the starting material.

Dargen's condensation of betaionone with monochloro-methyl acetate in strongly basic conditions gives "C_{14}-aldehyde" through an intermediate epoxide. C_{14}-aldehyde thus obtained is reacted with ethyl magnesiumbromide treated 1-pentol in an organic solvent to get a product, commonly known as 'oxenine'. The latter is selectively reduced at the acetylenic double bond with hydrogen using quinoline poisoned palladium catalyst, to get a product known as hydronynine. The latter containing one primary and one secondary hydroxyl group is selectively acetylated at the primary alcoholic centre followed by dehydration and rearrangement in presence of a strong acid to get vitamin A acetate. Trans-esterification of the product with ethyl palmitate would give vitamin-A palmitate.

A slight modification of the above routes was published in: (i) U.S. Pat. no. 2, 369, 156 by N. A. Milas, *1945*, and (ii) N A. Milas, *Science*, **103,** 581, 1946. Several other methods having some or major modification of the above have been described in the following references: (1) W. Oroshink, *J. Amer. Chem. Soc.*, **67,** 1627,*1945;* (2) J. F. Arens, D. A. Van Dorp, *Nature*, **157**, 190, *1946;* (3) J. F. Arens, D. A. Van Dorp, *Nature*. **160**, 189, *1947*; (4) J. F. Arens, D. A. Van Dorp, *Rec. Trav. Chim.*, **65,** 338, *1946*; (5) O. Schwarzkopf, H. J. Cahnmann, A. D.

Lewis, J. Swidinsky, H. M. Wuest., *Helv. Chim. Acta.*, **32,** 443, *1949*; (6) H. Linder, *Helv. Chim. Acta.*, **35,** 446 *1952;* (7) H. Pommer, *Angew. Chema*, **72,** 811, *1960*) using betaionone as the starting material. Another method studied extensively was the condensation of betaionone with the ethylester of 6-bromo 3-methyl hex-2-en-4-yoic acid by the Reformatsky reaction. The condensation product was subjected to dehydration, followed by selective hydrogenation at the acetylinic double bond to give ethylester of retinoic acid, which on reduction gave retinol.

The starting material for all the above synthesis had been betaionone; there are several methods for its synthesis. However, in our country none other than citral could be found to be a commercially suitable method for its synthesis. Lemongrass, grown extensively in India, specially in far-south in Cochin, on steam distillation gives an oil, commonly known as Lemon Grass Oil (L. G. O.) which contains 75-80% of citral in it. In effect, therefore, L. G. O. forms a starting material for betaionone.

Several other routes of synthesis without the use of betaionone have been reported, noteworthy among them was that reported by J. Attenburrow, A.F.B. Cameron, J. H. Chapman, R. M. Evans, B. A. Hems, A. B. A. Jansen and T. Walker, *J. Chem. Soc.*, 1094, *1952*] to start from 2, 2, 6 trimethylcyclohexanone. Several other interesting routes have also been investigated and an inquistive reader may like to go through them; (1) G. Wittig and U. Schllkopf *Ber.*, **87,** 1318, *1954* (2) U. Schollkopf, *Angew. Chem* , **71**, 260 *1959*, (3) H. Pommer, *Angew. Chem.*, **72,** 260, *1960*, (4) S. Trippett, *Advances in Organic Chemistry, Methods and Results (Ed.* by R. A. Rapheal, E. C. Taylor & H. Wynberg), Vol. 1, Interscience Publishers 1960, (5) S. F. Dyke, *The Chemistry of the Vitamins*, Vol-VI, 1965, Interscience Publishers). Since such methods are usually of academic interest and have limited commercial application in our country at this juncture I have refrained from dealing with them in this write-up.

8. Demand and Supply :

Blindness due to inadequate vitamin A intake is a matter of serious concern as every year nearly 10,000-12,000 children fall prey to blindness in India. To overcome this, the vitamin is being distributed by Government through various channels for quite some time. It is expected that this national programme will be intensified which would result in increased consumption.

Vitamin A is also used extensively in multivitamin preparations. The market for such preparations is increasing fast and it is expected that the trend will be maintained. Thus nearly 35-40 MMU of the vitamin representing 65-70% of the total available is consumed in the manufacture of various drug formulation.

A large amount of vitamin A is used for enriching hydrogenated oils under statutory orders. It is estimated that the vegetable oil industry must have consumed at least 14.25, 17 and 15.5 MMU respectively, during the last three years. Based on the projected increase of hydrogenated oil production during 1980-81 and 1984-85, the consumption of the vitamin by the vanaspati industry will be of the order of 18 MMU in 1980-81 and 22 MMU in 1984-85. Due to various reasons, the potency of vitamin A in hydrogenated oil decreases very fast, and therefore to maintain the level required by the Statutory Order, the manufacturers may have to add large excess of the vitamin.

Thus it is expected that the demand will increase steadily in the coming years and this can not be fully met with indigenous production. From the estimated demand figures, it appears that even after the Kerala unit comes into full production and assuming that the two existing producers come up to full installed capacity, a large gap of 65-70 MMU would develop by 1984-85. However, if imports are liberalised as a consequence, indigenous production may suffer. It would, therefore, be desirable to create additional capacities either by expansion of existing units or by establishing new units. A new unit of 65-70 MMU capacity will have benefit of the economics of production and will not be large enough to face problems of marketing the product. The advantages are expected to be larger if such capacity is created by expansion of existing units. Since capacity of this size would take some time to create, an expeditious decision in this regard is required.

As per the New Drug Policy, vitamin A is open for licencing to all sectors of the industry and, therefore, there is no restriction in procuring technology even from outside. In the choice of a technology, petroleum based starting materials would be more expensive, under Indian conditions, compared to agriculture based materials. Processes starting from betaionone would be more appropriate because it accounts for more than one-third of the material cost of vitamin A production and can be made from lemon grass oil which is produced commercially in the country.

DRUG INDUSTRY

General News

Compensation for Bengal Chemical acquisition

Under the Bengal Chemical and Pharmaceutical Works Ltd. (Acquisition and Transfer of Undertaking) Bill 1980, the Union Government will pay Rs. 5.02 crore for the acquisition of BCWP, Calcutta. A sum of Rs. 64000 (at the rate of Rs. 2,000/pm) will also be paid for the period for which the company's management has been taken over i.e. from December 1977 to the date the act comes into force.

According to the statement of the bill "it is necessary to acquire the undertakings of the company for the purpose of reconstructing and rehabilitating it so as to subserve the interests of the general public by augmenting production and distribution of different varieties of pharmaceuticals and chemicals".

The company showed a steady decline from 1969-70 onwards except for the years 1972-73 and 1974-75 and was being mismanaged also.

New drug introductions decline

According to drug industry sources, new drug introduction has gone down considerably during the last one year. The new Drug Price Control Order is said to be responsible for this situation. This order stipulates that all new introductions have to be under generic name instead of brand name.

The sources point out that in spite of this order public sector drug firms are printing generic as well as brand names and are also getting preferential treatment in the issuance of licences for the introduction of new drugs. The private industry, especially small and medium size, is finding it difficult to switch over to this arrangement because of the involvement of a huge amount of promotional expenditure. Any firm first introducing the drug will have to spend a lot. All this has led to a decline in new introductions.

Plan document for 5 to 30 per cent growth of certain drugs

Plan document listing the demand projections for 131 bulk drugs prepared by the Ministry of Petroleum, Chemicals and Fertilizers is reported to be in final stages of preparation.

Significant changes have been introduced in the projections made by the Planning Commission working group in 1978. List of drugs has been increased to 131 an increase of 9 drugs in the original list of 122 drugs proposed by Planning Commission. The percentage of annual growth rate for certain important drugs is as follows:

Rifampicin, 30; penicillin, 27; amoxycillin, 20; streptomycin, 5; chloramphenicol, 5; tetracycline, 10; sulphamethoxazole, 20; sulphaphenazole, 7.5; vitamin A, 15; vitamin B_1, 15; vitamin C, 15; tinidazole, 20; INH, 20; dapsone, 15; and salbutamol, 20.

Imported bulk drugs for export production

The Union Ministry of Petroleum, Chemicals and Fertilizers has finalized a scheme under which the drug firms will be given duty free canalised bulk drugs for export production. These drugs will be supplied off the shelf to the exporters at the international prices and to start with the scheme shall cover eleven drugs including ethambutol, tetracycline, iodine, gentamycin and chloramphenicol.

The intending exporters are expected to apply to CPC through the Basic Chemicals, Pharmaceuticals and Cosmetics Export Promotion Council for the release of these bulk drugs. Small scale units will get a preferential treatment in the allocation of raw materials.

Govt. for self-reliance in bulk drug production

Because the Government intends to assign priority to the public and private sectors, foreign drug companies will now have only a limited role in the production of bulk drugs and formulations. According to Mr. Veerendra Patil, Union Minister for Petroleum, Chemicals and Fertilizers, the aim of this policy is to enable the country achieve self-reliance in production and technology.

The multinational drug companies will be granted licences for producing drug formulations, provided the formulations are made from their own production of bulk drugs using high technology. The excess capacity of drug firms will be regularised in accordance with the new industrial policy. The criterion for regularisation will be the highest production achieved by a unit in any year during the three year period before 31 March, 1977.

Industry unhappy over capacity regularisation move

Drug industry has resented the Government move of regularising the excess capacity for drug formulations at the highest production achieved by a unit in the three year period ending March 31, 1977. Industry sources feel that this may aggravate the shortage of medicines as regularisation at pre-1977 level means a cut back in the production of several life saving drugs.

Apart from several formulations production of drugs like streptomycin, penicillin, oxytetracycline is much in excess of licenced capacities and this excess capacity exists both in Indian as well as foreign sectors. In fact some drugs in spite of their excess output are still in short supply and Government has neither allowed increase in the capacity for these drugs nor has given any fresh licence for the last many years.

The Industry feels that in view of the present shortage, basis for excess capacity regularisation should be 1980, which should have also a provision for 10 per cent automatic annual growth.

Industry suffering due to lack of fresh investment

Fresh investment in drug industry has come down because of, it is reported, unremunerative drug prices. The drug prices are frozen since 1978. The Industry is not committing fresh investment without being assured of a fair return on investment.

The Working Group on Drugs and Pharmaceuticals had estimated an additional investment of Rs. 150 crore in the public sector and Rs. 100 crore in the private sector in bulk drugs during the sixth plan period (1978/79—1982/83). But the real investment was quite less. Public sector invested Rs. 60 crore, which is only two fifth of the investment envisaged for public sector companies. As far as private sector is concerned, very little of the targeted investment has taken place.

Bulk drug price hike implementation put off

Although the Government has decided in principle to raise the prices of certain bulk drugs, formal orders will be issued only after a few months. The decision favours price increase of certain drugs and decrease in price of others.

The Union Cabinet has given permission to the Ministry of Petroleum, Chemicals and Fertilizers to start the task of price revision taking into account the increased cost of petroleum based raw material during the last few years. It would take at least two months before the first revision in bulk drugs prices could be expected. The BICP (Bureau of Industrial Costs and Prices) recommendations which were considered by the cabinet will go to the Ministry of Petroleum, Chemicals and Fertilizers. Finally an official committee would clear these recommendations.

INSA award for young scientists

Fifteen scientists have been selected by the Indian National Science Academy for the award of "Science Academy medals for young scientists for the year 1980". The awardees are:—

Dr Prabha Agarwal, University of Indore, Indore; Dr. D. V. Amla, National Botanical Research Institute, Lucknow; Mr. R. Balasubramanium, Dr. M. A. Barma, and Mr. Madhav V. Nori, Tata Institute of Fundamental Research, Bombay; Mr. D. K. Chakrabarti, Dr. D. Pandey, Banaras Hindu University, Banaras; Dr. S. S. Mehetra, All India Coordinated Cotton Improvement Project, Mahatma Phule Krishi Vidyapith, Ahmednagar; Dr. N. Pattabhiraman, Indian Institute of Science, Banglore; Dr. Sudhir Paul, All India Institute of Medical Sciences, N. Delhi; Dr. S.S. Pillai, Calcutta Medical Research Institute, Calcutta; Mr. E. S. P. Reddy, Centre for Cellular and Molecular Biology, Hyderabad; Dr. N. Sathyamurthy, Indian Institute of Technology, Kanpur; Dr. A. K. Saxena, University of Roorkee, Roorkee; and Mr. V. N. Vasudev, Deptt. of Mines and Geology, Bangalore.

The award instituted in 1974 comprises a medal, cash award of Rs. 1,5 0/- and a research grant of Rs. 5,000/- to each awardee. The presentation will be made at the 68th session of Indian Science Congress at Varanasi in January 1981.

Non-utilization of licences causes drug shortages

An official study has pointed out that 45 industrial licences issued between January 1972 and June 1977 and 44 letters of intent issued between January 1975 and June 1978 have not been used. These licences cover 143 drugs which are held by 54 different companies. Of these drugs, some important ones are pethidine HCl, nitrofurantoin, sulphaphenozole, vitamin B_6, sulphadimethoxine, niacinamide, chloroquin, frusemide, ethambutol, cephalorindine and griseofulvin etc.

An analysis of other data shows that the three public sector companies have ten industrial licences and 8 letters of intent for 59 bulk drugs, forty Indian sector companies have 31 licences and 27 letters of intent for 68 bulk drugs, and ten multinationals are holding 3 licences and 16 letters of intent for 16 bulk drugs.

Non-utilization of licences has led to a situation in which all the targets of bulk drug production have gone haywire resulting in a serious drug shortage. The Government had, therefore, no option but to resort to bulk imports to meet the minimum requirements. The imports were Rs. 150 crore in 1978-79 compared to Rs. 82 crore in 1976-77, almost a 100 per cent rise in just two years.

In a situation where import costs are rising and the gap between availability and demand is increasing, the Government has no option but to devise ways and means of ensuring that industrial licences issued are implemented within the stipulated time. Companies that have defaulted in the past may suffer a disadvantage in securing fresh capacities during the coming sixth plan.

Big rise in drug production expected

The anticipated increase in drug prices will give the sagging drug production a big boost, according to Mr. Veeredra Patil, the Union Minister of Petroleum and Chemicals. It is well known that major drug formulators had cut their production on the plea that the prices were unremunerative. However, only certain brand named drugs are in short supply and not all. The present shortage is partly due to the policy which requires major manufacturers to give 50 per cent of their basic drugs manufactured to the unorganised sector. Since the unorganised sector lacks the resources to market their products this leads to shortage in certain areas.

Goa gets drug formulation unit

The Union Government has issued a letter of intent for a Rs. 2 crore drug formulation plant to be set up in Pernem Taluka of North Goa. The Goa Government has already made available the land. The Project is being set up jointly by Economic Development Corporation of Goa and the Hindustan Antibiotics Ltd.

Sino-Japanese pharmaceutical tie-up

Otsuka Pharmaceutical Co., a Japanese general medicine manufacturer, has signed a 20 year contract with China's National Drug and Medicine Control Agency under which a pharmaceutical plant will be established in south—east China. The plant is expected to cost Yen 1.6 billion and will be shared on a 50:50 basis.

The plant is likely to be commissioned by January 1982 and is expected to produce an estimated six million plastic bottles each containing 1.65 ounce of fluids such as glucose.

Arab countries decide to shift WHO Regional Office

A conference of the Arab Health Ministers which was held in Amman (Jordan) has decided that the WHO Regional Office for the Eastern Mediterranean be moved from Alexandria (Egypt) to Amman and that an Arab Centre be set up for Documentation on local pharmaceutical manufacture and other administrative issues.

Scrip, No. **512,** 12 (4 Aug. 80)

ASEAN collaboration in health programme

Indonesia, Malaysia, Thailand, Singapore and Philippines, the member countries of ASEAN have decided to include pharmaceuticals, biologicals and traditional medicines in an eight point programme to promote health collaboration within the ASEAN network. A declaration issued after a joint meeting held in Manila includes the following areas for collaboration: primary health care, disease control, nutrition, health manpower development, environmental & occupational health and mental health.

Scrip, No. **514,** 7 (13 Aug. 80)

Company Reports

Sandoz to benefit most by capacity expansion

Under the new Industrial Policy Resolution, Government has permitted the regularisation of excess capacity. Sandoz is going to be the most benefited under this scheme because its 9 products will be regularised under the new policy. This scheme has mainly benefited multinationals and Indian monopoly houses which will account for the two thirds of the excess capacity that is going to be regularised. This finding has been reported by Dr. S. K. Goyal of the Indian Institute of Public Administration.

Nationalisation of Bengal Immunity soon

Bengal Immunity may be nationalised very soon. Established in 1919, it manufactures many products such as sera and vaccines, drugs and hormones. After 1972-73, it started incurring losses and between 1973 and 1977 the cumulative losses were more than Rs. 1 crore. The Government took over its management in 1978 and now to provide W. Bengal a stable pharmaceutical industry it is going to be nationalised. The two other sick units currently under state control are Bengal Chemicals and Smith Stanistreet.

Enhanced dividend by Zandu Pharmaceuticals

For the year ending March 31, 1980, Zandu Pharmaceuticals Works Ltd. has announced an equity dividend of Rs. 14 compared to Rs. 13 for the year before.

Zandu sales have gone up to Rs. 2.69 crore and the gross profit is Rs. 18.88 lakh against Rs. 20.95 lakh in the preceding year.

Pfizer and E. Merck decide to dilute equity

Responding to the Government's call for dilution of their foreign equity, two drug multinationals namely Pfizer and E. Merck have decided to dilute. Pfizer having a foreign equity of 75 per cent proposes to come down to 60 per cent and E. Merck having 60 per cent may slide down to 40 per cent.

Meanwhile the Government is examining the companies' cases for expansion and diversification.

Boehringer-Knoll sales up

For the year ending April 1980, Boehringer-Knoll sales and other incomes were Rs. 10.31 crore compared to Rs. 9.32 crore for the corresponding period of 1979. The profit before tax slumped to Rs. 33.56 lakh from Rs. 40.05 lakh. After providing for Rs. 13.10 lakh for taxation and Rs. 6.60 lakh as investment allowance, the net surplus came out to be Rs. 13.86 lakh. The company has thus maintained a dividend at 12 per cent for the year ending April, 1980.

The company is going ahead with its project of doubling up the capacity of chloramphenicol which is expected to be completed this year. The company has also received letters of intent for the manufacture of alpha methyl dopa and theophylline. For this the company has purchased land in backward area of Patalganga in Maharashtra.

Research and Development

Chloroquin know-how to be improved

The total indigenous production of chloroquin phosphate in the country is about 40 tonnes against the need of 250 tonnes annually. This gap is filled through imports from United States, Britain and Hungary. Since the present Indian technology is not as advanced as that being used by multinationals, the efforts to acquire improved technology were on for the last few years. Efforts with some French and German firms were, however, not successful in this direction.

UNIDO sometimes back offered to help India in getting technology from Hungary but that proved to be a tough bargain. Hungary wanted India to import whole of its requirement from them pending the transfer of improved technology. All this made the Government to realise that it is much better to develop their own technology rather than complying to the demands of Hungary. Now the R&D centre of Indian Drugs and Pharmaceuticals Ltd., Hyderabad has earnestly, started the work on this project and an early breakthrough is expected.

Safflower oil: a cure for hangover

Two alcoholic patients who could not be treated of their dysphoria or hangover even after the treatment with isocarboxazid and lithium, when given a 3 g dose of safflower oil, all symptoms of hangover abated within 20 minutes in 1 patient and within a few days in the other. Safflower oil is a good source of linoleic acid, a precursor of prostaglandin E_1. As low prostaglandin E_1 may add to tremors and dysphoria in alcoholics, supplementation with safflower oil may benefit some alcohol withdrawl cases.

British Medical J. **281,** 453 (6 Aug. 80)

Propranolol and nifedipine found effective in angina

For patients suffering from angina pectoris, β-blockers are either found to be inadequate or unsuitable. A trial on patients with severe exertional angina pectoris, nifedipine and propranolol have been found to show antianginal effect. The drugs taken together give better results than taken singly.

It was also found that anginal pain and consumption of nitroglycerin were significantly reduced by both drugs but propranolol was definitely better. Also the higher dose of propranolol was no better than the lower dose, but nifeidipine in higher dose was significantly more effective that the lower dose. The higher dose of the combination reduced anginal pain and nitroglycerin consumption even further.

Side effects were generally mild coldness or numbness of the fingers, the latter being most common side effect with propranolol and swollen ankles with nifedipine.

British Medical J., **280,** 184 (19 July 80)

Dantrolene for malignant hyperthermia

The US Food and Drug Administration has approved the marketing of Dantrolene sodium (Dantrium; Norwich Eaton) as a muscle relaxant for the *iv* treatment of malignant hyperthermia. The first clinical sign of this is muscle rigidity followed by tachycardia, arrhythmias, tachypnea, rapidly rising temperature, acidosis, hyperthermia and death. At the very first sign of muscle rigidity anaesthesia should be stopped and symptomatic treatment started.

On prolonged use major adverse reactions are hepatotoxicity and pleuropericardial reactions. It is given by rapid *iv* push starting with 1 mg/kg, continuing till symptoms subside or upto a maximum of 10 mg/kg. Immediate *iv* treatment is life saving and the regimen may be repeated if symptoms recur.

Inpharma, No. **250,** 3 (16 Aug. 80)

Oral contraceptives may effect breast milk

Some lactating mothers were given a combination of oral contraceptives such as levonorgestrel (*d*-norgestrel), megestrol-acetate and ethinyl estradiol to see their effect on total nitrogen, non-protein nitrogen, lactose and the individual milk proteins, lactoferrin, α-lactalbumin and albumin.

The mean milk volumes of the mothers remained within normal limits before and after starting and no significant effects were observed in milk levels of α-lactalbumin, protein or non-protein nitrogen in breast milk at any time. However, albumin and lactoferrin levels were reduced considerably compared to controls.

Inpharma, No. **251,** 14 (23 Aug 80)

REGULATORY NEWS

Drug industry opinion sought to weed out irrational drug combinations

The Drugs Controller of India, Mr. S. S. Gothoskar, has sought the opinion of Pharmaceutical Associations about the weeding out of certain fixed dose combinations.

In the country today, are marketed a large number of drug formulations many of which have no therapeutic rationale and some are even harmful. The Drugs Consultative Committee—a statutory body appointed under the Drugs and Cosmetics Act—which consists of the representatives of the Central and State Drugs Control Organisations had recently considered the question of marketing of irrational combinations in the country and had appointed a sub-committee to go into this question. The sub-committee had co-opted experts in pharmacology and medicine and screened a large number of fixed dose combinations marketed in the country with due regard to the criteria laid down by the WHO for marketing of fixed dose combinations.

The sub-committee examined 34 categories of fixed dose combinations and felt that 23 categories had no therapeutic rationale for their marketing. Of the 23 categories, 16 categories were felt to be harmful combinations and required immediate action for ban on their manufacture in the country; remaining 7 categories, it was felt, could be weeded out over a specified period of time. These two different types of categories of fixed-dose combinations are listed in the statement given below along with the reasons which weighed with the sub-committee for recommending their weeding out.

A. Categories of fixed-dose combinations to be weeded out immediately

1. *Fixed Dose Combinations of Steroids*

Fixed dose combinations of steroids with any other category of drugs should not be allowed as they are considered harmful for the following reasons:—

(a) The adrenal suppression accompanying steroid therapy leads to symptoms and signs of adrenal insufficiency, if the steroid is abruptly withdrawn.

(b) It is difficult to titrate the dose of a steroid when it is present in fixed dose combinations with other drugs.

2. *Fixed Dose Combinations of Amidopyrine*

Amidopyrine is considered toxic because:—

(a) It causes high incidence of agranulocytosis.

(b) In some individuals, it may cause a sharp fall of total leucocyte count associated with chill, fever, headache and pain in muscles and joints following the administration of the drug.

3. *Fixed Dose Combinations of Chloramphenicol*

Fixed dose combination of chloramphenicol with any other category of drug is considered harmful for the following reasons and should not be allowed:—

(a) Chloramphenicol is the commonest drug which causes pancytopenia and peripheral blood changes including leucopenia, thrombocytopenia and aplasia of the bone marrow. This reaction is not related to dose and when bone marrow aplasia is complete, the fatality rate is almost 100%.

(b) Patients receiving chloramphenicol must be checked repeatedly for blood studies which is, however, generally not done in the case of patients receiving fixed dose combinations of chloramphenicol.

4. *Fixed Dose Combinations of Ergot*

Fixed dose combinations of ergot with quinine, ethinyl estradiol etc. should not be allowed. Such combinations are considered harmful for the following reasons:—

(a) They may cause uncontrollable bleeding and may lead to serious consequences.

(b) They may cause many harmful side effects.

5. *Fixed Dose Combinations of Vitamins with Anti-Inflammatory Agent & Tranquillisers*

Fixed dose combinations of vitamins with anti-inflammatory agents and tranquillisers should not be allowed. Such combinations are considered' irrational for the following reasons:—

(a) There is no definite role of vitamins in the management of inflammatory disorders and therefore a fixed dose addition of vitamins in such preparations will be irrational.

(b) Similarly there is no rationale for adding vitamins to tranquillisers.

6. *Fixed Dose Combinations of Atropine in Analgesic Anti-pyretics*

Fixed dose combinations of atropine in analgesic antipyretic should not be allowed as atropine may reduce efficacy of antipyretics by blocking sweating response.

7. *Fixed Dose Combinations of Analgin*

Fixed dose combinations of any category of drug with analgin in oral dosage form are considered generally harmful as analgin is potentially a toxic drug and may cause agranulocytosis except for some combinations which may have therapeutic rationale e.g., with neurovitamins. However, fixed dose combinations with analgin in injectable form may be continued to be allowed as these are generally meant to combat an acute attack of pain, and that injectables are less likely to be misused.

8. *Fixed Dose Combinations of Yohimbine & Strychnine with Testosterone & Vitamins*

Fixed dose combinations of yohimbine and strychnine in a formula containing testosterone and vitamin B_{12} should not be allowed. Such combinations are considered harmful and irrational for the following reasons:—.

(a) Yohimbine easily penetrates the CNS and can cause central excitation including rise of B. P. and heart rate, hyper-excitability and tremor.

(b) There is no convincing evidence regarding the aphrodisiac effect of yohimbine and the drug has no proven therapeutic value.

(c) There is no rational basis for the use of strychnine in therapy and therefore no justification for its use in any proprietary medicine.

(d) There is a very narrow margin between the therapeutic dose and the toxic dose of strychnine.

9. *Fixed Dose Combinations of Iron with Strychnine, Arsenic, & Yohimbine*

Fixed dose combinations of iron with strychnine, arsenic and yohimbine should not be allowed as there is no rationale of such combinations and such combination can cause harmful side effects.

10. *Fixed Dose Combinations of Sodium Bromide/Chloral hydrate with Other Drugs*

Fixed dose combinations of sodium bromide/chloral hydrate with any category of drug are considered irrational and harmful for the following reasons:—

> Use of both sodium bromide and chloral hydrate have become obsolete, as there are safer hypnotic drugs available today and their therapeutic concentration in blood is very close to their toxic levels.

11. *Fixed Dose Combinations of Tetracycline, Analgin with Vitamin C*

Fixed dose combinations of tetracycline, analgin etc. with vitamin C should not be allowed as there is no rationale of such combinations.

12. *Fixed Dose Combinations of Ayurvedic Drugs with Modern Drugs*

Fixed dose combinations of Ayurvedic drugs and potent allopathic drugs like stilboestrol could be very harmful and there is no adequate evidence of the safety of the interactions of drugs of these two systems of medicine.

13. *Fixed Dose Combinations of Phenacetin*

Fixed dose combinations of any category of drugs with phenacetin should not be allowed, as the question of banning phenacetin because of its potential toxicity (nephropathy, methaemoglobinemia, hemolytic anemia as a consequence of chronic overdosage) is under active consideration of the Government.

14. *Fixed Dose Combinations of Chloramphenicol with Streptomycin*

Fixed dose combinations of chloramphenicol with streptomycin should not be allowed as chloramphenicol being potentially a toxic drug, its use should be kept restricted to enteric fever only.

15. *Fixed Dose Combinations of Penicillin with Streptomycin*

Fixed dose combinations of Penicillin with Streptomycin should not be allowed

16. *Fixed Dose Combinations of more than one Anti-histaminics*

Fixed dose combinations of more than one anti-histaminics in oral dosage form should not be allowed as the differences between their action is but marginal.

B. Categories of fixed dose combinations to be weeded out over a specified time

1. *Fixed Dose Combinations of Anti-histaminics in Antidiarrhoeals*

Fixed dose combinations of sedative antihistaminic in antidiarrhoeal preparations may be permitted provided all ingredients are in adequate therapeutic doses.

2. *Fixed Dose Combinations of Penicillin with Sulphonamides*

Fixed dose combinations of penicillin with sulphonamides are considered irrational for the following reasons:—

(a) The combination of penicillin, a bactericidal drug and sulphonamide, a bacteriostatic drug may cause antagonism.

(b) There is a risk of development of bacterial resistance to both the drugs.

3. *Fixed Dose Combinations of Anti-histaminic with Tranquilliser*

Fixed dose combinations of antihistaminics having patent sedative properties (for example, diphenhydramine dimenhydrinate, tripelennamines, pyrelamine, antazoline, methapyrilene etc.) with tranquillisers are considered irrational for the following reasons:—

Such combinations may cause enhanced sedation, which may interfere with the patient's day time activity and dull the mind and slow the reflex activity.

4. *Fixed Dose Combinations of Tranquillisers, Anti-histaminics and Analgesics*

Fixed dose combinations of tranquillisers with anti-histaminics and analgesics in oral dosage form are considered irrational for the following reasons:—

(a) Such combinations may cause lot of unwanted sedation, which may interfere with the patient's day time activity and dull the mind and slow reflexes.

(b) There may not be many clinical situations which would need a fixed dose combination of these 3 categories of drugs and there will be unnecessary drugging. However, fixed dose combinations of these drugs in injectable form may be allowed as injectables are not likely to be misused.

5. *Fixed Dose Combinations of Vitamins with Analgesics*

Fixed dose combinations of high dose Vitamins with analgesics should not be allowed unless there is adequate evidence in support of the rationale of such combination.

6. *Fixed Dose Combinations of Paracetamol with Anti-histaminics & Tranquillisers.*

Fixed dose combinations of paracetamol with anti-histaminics and tranquillisers should not be allowed as there is hardly any clinical situation which should demand a fixed dose combination of antipyretic, an antihistaminic and a tranquilliser. However, fixed dose combinations of paracetamol with an antihistaminics and paracetamol with tranquillisers may be allowed provided the formula contains an adequate dose of such ingredient.

7. *Fixed Dose Combinations of Prophylactic Vitamins in Anti-TB Drugs*

Fixed dose combinations of vitamins in prophylactic doses in anti-TB drugs should not be allowed as such combinations lack any rationale. However, combinations having a therapeutic rationale such as INH + B_6 may be allowed.

Vitamin Cimport canalised

In a recent modification in the import policy, the import of vitamin C has been canalised through State Chemicals and Pharmaceutical Corporation. Earlier its import was banned and a policy regulating its distribution was framed (*See* This bulletin 3, No. 8, p 251). Now this modification will regulate the imports to fill the gap between domestic production and demand.

Two stage clinical trials recommended in UK

The main recommendation of the Prof. Grahame-Smith working party is reported to be for the introduction of a two stage clinical trial system. The first stage trials would be strictly limited in terms of the number of patients and the duration of therapy and would be carefully monitored. For these, stress on animal investigations will be less compared to the currently required one. The second stage would comprise all the investigatory work needed for a product licence application to the UK authorities with some modification of the animal testing requirements.

Scrip, No **512,** 3 (6 Aug. 80)

Specifications for pharmaceutical preparations: WHO report published

The 27th report of World Health Organisation's "Expert Committee on specifications for Pharmaceutical Preparations" has recently been published. It contains recommendations on tests used for the quality control of solid and oral dosage forms such as tablets and capsules and a general review of drug quality control systems. This report will be used by the 54 member nations that have now agreed to participate in the, "Certification scheme on the quality of pharmaceutical products moving in international commerce".

International Drug Regulatory Monitor, No. **87,** 19 (Aug. 80)

Interferon use regulated

Because of the meagre availability of interferon its use has been restricted in Britain. A statement issued by the Co-ordinating Committee on Cancer Research, a committee representing the major funding bodies for cancer research, says that now onwards the first priority must be to use it in carefully designed clinical trials to establish its effectiveness. Interferon will not be provided to patients who are not in a clinical trial.

Pharmaceutical J., **225,** 129 (2 Aug. 80)

Expiry date exemption for allergenic extracts

The US Food and Drug Administration has exempted allergenic extracts from expiry dating and stability testing requirement till reliable tests for stability of drug products over a period of time are fully developed. So far, there are no standards of potency for these products in USA. Standards are difficult to frame due to complexity of allergenic extracts and without standards of potency, stability tests can not be conducted. Hence no expiry date can be mentioned without valid stability tests.

Scrip, No. **511,** 13 (4 Aug. 80)

Captopril may have nephrotoxic side effects

A few hypertensive patients who were given Squibb's Capoten (Captopril) were found to have nephrotoxic side effects. The doctors working at the Cornell Medical Centre, New York, have advocated that therapeutic advantages of this new agent must be evaluated in the context of its possible nephrotoxic side effects.

Six of the 81 patients developed proteinuria. In four patients it subsided in four months but persisted in the remaining two. It resulted in hypoalbuminaemia and hypercholesterolaemia in them.

J. American Medical Association, **244,** 346 (1980)

US FDA cautions captopril users

Cardiovascular and Renal Drugs Advisory Committee has issued the following statement for the users of captopril, "Captopril should be limited to patients whose hypertension fails to respond to, or who develop intolerable side-effects with combinations of other standard antihypertensive agents, usually including a diuretic, a sympathetic blocking agent (including a betablocker) and a vasodilators".

Scrip, No. **515,** 14 (18 Aug. 10)

CSM lists clofibrate as potentially hazardous

British Committee on Safety of Medicine has issued a "yellow warning" notice on the potential hazards of the widespread use of clofibrate. Results from a long term trial of clofibrate in the primary prevention of ischaemic heart disease indicate that men treated with the drug have a significantly higher mortality rate than a comparable control group.

However, hazards are not such that clofibrate should be banned but its use should be restricted to certain specified conditions like exudative diabetic retinopathy, xanthomata and specific hyperlipoproteinaemias.

Pharmaceutical J., **225,** 238 (30 Aug. 80)

New Drug Standards proposed in Canada

Health Protection Branch of Canada has published "Draft of Preclinical Toxicologic Guidelines" proposing standards for preclinical testing of new drugs. These standards are parallel to those published by the European Economic Community.

The new guidelines cover acute, subacute and chronic toxicity tests to general toxic effects in animals as well as special tests for carcinogenicity, teratogenicity and mutagenicity. These toxicity guidelines support the Canadian "Standard for Good Laboratory Practice in Non-Clinical Laboratory Studies", which calls for establishing of protocols pertaining to all non-clinical laboratory studies.

International Drug Regulatory Monitor, No. **87**,4 (Aug. 80)

Cancer causing chemicals identified

The chemicals which are historically associated with cancer in humans have been listed in the "First Annual Report on Carcinogens" of the United States Department of Health and Human Services. The chemicals are:

1. Aflatoxins
2. 4-Aminobiphenyl
3. Arsenic compounds
4. Asbestos
5. Auramine
6. Benzene
7. Benzidine
8. N, N Bis (2-Chloroethyl)-2-Naphthylamine
9. Bis (Chloromethyl)ether
10. Cadmium
11. Chloramphenicol
12. Chloromethyl methylether
13. Chromium
14. Cyclophosphamide
15. Diethylstilboestrol
16. Hematite
17. Isopropyl oils
18. Melphalan
19. Mustard gas
20. 2-Naphthylamine
21. Nickel
22. Oxymetholone
23. Phenacetin
24. Phenytoin
25. Soots, tars and oils
26. Vinyl chloride.

International Drug Regulatory Monitor, No. **87,** 21 (Aug. 80)

USFDA asks for precaution statement on neuroleptics labels

US Food and Drug Administration has notified that with effect from Dec. 8, 1980, neuroleptic drug products will carry a warning of the drug's potential risk to patients through their prolactin serum raising effect. Rauwolfia alkaloids are temporarily excluded from the new requirement. Lithium carbonate is permanently exempted because it does not raise serum prolactin levels.

Scrip, No. **515,** 8 (18 Aug. 80)

Bubble bath products to carry label warning

US Food and Drug Administration has made it compulsory for all the bubble bath products to carry a label warning from Aug. 19, 1981. Prolonged use of these products may cause irritation and many reports indicate their association with skin irritation and urinary tract infections. The problem ingredients are the foaming agents themselves which on long and repeated use can remove the skin's natural oil and cause drying, fissuring, irritation and inflammation. The following label warning has been issued:

"*Caution*—Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness or itching occurs. Consult your physician if irritation persists. Keep out of reach of children". Products meant for children's use may contain additional "except under adult supervision".

International Drug Regulatory Monitor, No. **87,** 20 (Aug. 80)

Drug having bioavailability problem will be banned in Japan

A notification issued by the Japanese Ministry of Health and Welfare, say that any drug which fails to substantiate its bioavailability claims will be cancelled and if it is a Japanese pharmacpoeia drug it shall be deleted from it. Manufacture of such drug shall be discontinued at once and the product in the market shall be withdrawn.

The notification further provides that if availability is limited to part of the claimed indications or if a change in composition is required on the ground of impracticable large dosage strength, then the manufacturer or importer shall have to file a supplemental application so as to conform with the results of the revaluation.

Japan Medical Gazette, **17,** 8 (20 Aug. 80)

INDUSTRIAL LICENCES AND LETTERS OF INTENT

ISSUED DURING JUNE 1980

Sl. No.	Name and address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence, No. and date
	Licences				
1.	Unichem Laboratories Ltd. Unichem Bhawan, S. V. Road, Bombay.	Roha Distt. Colaba	Prenylamine lactate	500 kgs	New Article CIL: 145/80 dated 11.6.80
	Letters of Intent				
1.	Andhra Citrates Ltd. 5-9-47/6 Asra Manzil, Bashir Bagh, Hyderabad.	Medchal, Distt. Rangareddy	1. Citric acid BP/IP quality 2. Calcium sulphate (filter acid quality)	400 tonnes (exis.) 680 tonnes (after expn.) 600 tonnes (exis.) 1020 tonnes (after expn.)	Substantial Expenses LI: 250/80 dated 16.6.80
2.	The Bengal Immunity Co. Ltd. 153 Lenin Saranee, Calcutta.	Baranagore. Calcutta	Amoxicillin Capsules (250 mg)	20,00,000 Capsules	New Article LI: 206/80 dated 10.6.80
3.	Raptakos, Brett & Co. Ltd. 47, Dr. Annie Besant Road, Worli, Bombay.	Roha, Distt. Colaba	Benorylate (basic manufacture)	50 tonnes	New Article LI: 235/80 dated 12.6 80
4.	Dr. Subhash A. Nerukar, 46, Narayan Baugh, Indore.	Indore	1. Chloroquine phosphate 2. Chloroquine sulphate	18 tonnes 15 tonnes	New Unit LI: 259/80 dated 18.6.80

Sl. No.	Name and address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence, No. and date
5.	Shri Vinod Kumar Jain, 36-A, Friends Colony (East) New Delhi.	Faridabad	Ampicillin	50 tonnes	New Unit LI: 198/80 dated 10.6 80
6.	Uniloids Ltd., 3-6-524 Himayatnagar, Hyderabad.	Hyderabad	(*i*) Tinidazole (*ii*) Sulfamethoxazole (*iii*) 19 Formulations:	40 tonnes 25 tonnes corresponding to consumption of bulk drug	New Article LI: 267/80 dated 18.6.80
			Formulation Tablets		
			1. Methyl dopa	1 lakh	
			2. Ethambutol	3 ,,	
			3. Erythromycin	1 ,,	
			4. Xanthinol nicotinate	7.5 ,,	
			5. Xanthinol nicotinate	1 ,,	
			6. Betamethasone	5 ,,	
			7. Cyclophosphamide	3 ,,	
			8. Promalgin	200 ,,	
			9. Analgin	100 ,,	
			Bulk Drugs Name		
			1. Methyl dopa	28 kg	
			2. Ethambutol	66 ,,	
			3. Erythromycin	28 ,,	
			4. Xanthinol nicotinate	415 ,,	
			5. Betamethasone	147 ,,	

Contd.

Sl. No.	Name and Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence, No. and date
			6. Cyclophosphamide	20 kg	
			7. Analgin	11,760 ,,	
			8. Paracetamol	5,250 ,,	
			9. Caffeine	2,100 ,,	
			10. Indomethacin	28 ,,	
			11. Vitamin B_1	210 ,,	
			12. Framycetin sulphate	25 ,,	
			13. Neomycin sulphate	65 ,,	
			Capsules		
			1. Indomethacin	10 lakh	
			2. Combigesic	48 ,,	
			Ointment		
			1. Framycetin sulphate	2 lakh	
			2. Betamethasone	1.5 ,,	
			3. Betamethasone	0.2 ,,	
			4. Neomycin sulphate	1 ,,	
			5. Neomycin sulphate	3 ,,	
			6. Xanthinol nicotinate	1 ,,	
			Drops		
			1. Framycetin sulphate	1 lakh	
			Powder		
			1. Neomycin sulphate	2 lakh	

NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	Generic Name	Trade Name	Manufacturer	Country
1.	*Analgesic*			
	Buprenorphine	Temgesic	Reckitt & Colman	Malaysia/ Singapore
	Nalbuphine	Nubain	Endo	Malaysia
2.	*Anthelmintic*			
	Flubendazole	Flumoxal	Janssen	Belgium
3.	*Antiarrhythmic*			
	Disopyramide	Rythmical	Unipharm	Israel
	Mexiletine	Mexilen	Rafa	Israel
4.	*Antibacterial*			
	Bacampicillin	Bacacil	Pfizer	Italy
	Cephalexin	Cephalexin-Ika	Ikapharm	Israel
	Cephapirin	Cefatrexyl	Bristol	Malaysia/ Singapore
	Netilmicin	Netromycin	Schering	Philippines
	Pivmecillinam	Selexid	Leo	Malaysia/ Singapore
5.	*Antidepressant*			
	Nomifensine	Merital	Hoechst	Malaysia/ Singapore
6.	*Antihyperlipidemic*			
	Clofibrate Aluminium	Alufibrate	Nikken Chemical	Japan
7.	*Antihypertensive*			
	Prazosin	Minipres	Pfizer	Spain
8.	*Antihypertensive/diuretic*			
	Prazosin+polythiazide	Minizide	Pfizer	USA
9.	*Anti-inflammatory*			
	Meclofenamate	Meclomen	Parke Davis	USA
	Proquazone	Biarison	Sandoz	Malaysia/ Singapore
	Tolmetin	Tolectin	McNeil	Malaysia

Sl. No.	Generic Name	Trade Name	Manufacturer	Country
10.	*Antineoplastic*			
	Ftorafur	Ftoral	Abic	Israel
	Lomustine	CCNU Abic	Abic	Israel
	Mopidamol	Repenton	Thomae	W. Germany
11.	*Antiulcer agent*			
	Tripotassium dicitrate bismuthate (tablets)	De-Nol	Gist-Brocades	New Zealand
12.	*Antiviral*			
	Vidarabine	Vira-A Parenteral	Parke-Davis	UK
13.	*β-Blocker*			
	Metipranolol	Disorate	Boehringer Mannheim	Malaysia/ Singapore
	Metoprolol	Lopresor	Geigy	Argentina
14.	*β-Blocker/diuretic*			
	Pindolol + Clopamide	Viskaldix	Sandoz	Malaysia/ Singapore
	Propranolol + bendrofluazide	Inderetic	ICI	S. Africa
15.	*Bronchodilator*			
	Eprozinol	Alecor	Andromaco	Argentina
	Fenspiride	Pneumoral	Servier	Malaysia/ Singapore
16.	*Calcium regulator*			
	1-α-Hydroxycholecalciferol	One-Alpha	Leo	Malaysia/ Singapore
	1α-Hydroxy vitamin D_3	Alpha D_3	Teva	Israel
17.	*CNS stimulant*			
	Vinpocetine	Cavinton	Gedeon Richter	Malaysia/ Singapore
18.	*Depot contraceptive*			
	Norethisterone enanthate	Noristerat	Schering AG	Indonesia
19.	*Gallstone dissolving agent*			
	Chenodiol (Chenodeoxycholic acid)	Chendol	Weddel	New Zealand/ S. Africa/ Australia

Contd.

Sl. No.	Generic Name	Trade Name	Manufacturer	Country
20.	*Glaucoma treatment*			
	Pilocarpine	Ocusert	Abic	Israel
	Timolol ophthalmic	Tiloptic	Teva	Israel
21.	*Hypnotic*			
	Triazolam	Halcion	Upjohn	France/New Zealand
22.	*Topical corticosteroid/antimicrobial*			
	Fluprednylidene+ gentamicin+ chlorohydroxyquinoline	Gentacortin	E. Merck	Indonesia
23.	*Uterine relaxant*			
	Ritodrine	Yutopar	Ethnor	New Zealand

BOOK REVIEWS

Publications of the World Health Organization 1973-1977. A bibliography, World Health Organization, Geneva, 1979, Pages 388, Price: Sw. fr. 40.-.

This bibliography covers the works published by the World Health Organization during the five-year period 1973-1977.

The volume is a trilingual edition, in English, French and Spanish; and, includes, for the first time, the publications issued by the various WHO regional offices and by the International Agency for Research on Cancer (IARC).

The bibliography consists of seven parts: (1) technical articles and publications arranged in alphabetical order, first by subject headings based on the classification used in the *Index Medicus*, and then by author, unsigned works being arranged alphabetically by title; (2) administrative and general articles, listed alphabetically under broad subject headings; (3) an index of authors; (4) an index of countries and areas; (5) an alphabetical list of French words guiding the French-speaking reader to the English subject headings; (6) a similar listing in Spanish for the Spanish-speaking reader; and (7) three separate check-lists, in English, French, and Spanish of the various series published by WHO headquarters, the regional offices, and IARC.

Prefacing the bibliography is a short account of the main features of WHO publications intended to guide the reader in the use of the bibliography, followed by a description of the arrangement of the material included therein, and an explanation of the symbols used to indicate the language or languages of publication of each item.

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Tuberculosis case-finding and chemotherapy: Questions and answers

By K. Toman, World Health Organization, Geneva, 1979, Pages 240, Price: Sw. fr. 32.-.

For many years the World Health Organization and the International Union against Tuberculosis have been advocating a modern simplified technology of tuberculosis control that is the outcome of three decades of research and large-scale trials. The effective application of the results implies a national tuberculosis programme, the principles of which have been outlined by the WHO Expert Committee on Tuberculosis. This concept abandons the vertical, specialist-centred structure of tuberculosis services (including the traditional tuberculosis sanatorium). The new approach widens the operational basis of tuberculosis control by involving non-specialist physicians, nurses, technicians and other categories of health workers and health administrators.

To satisfy the demand for detailed information on the scientific basis of modern tuberculosis control, Dr Kurt Toman, drawing on his long experience in the training of key tuberculosis staff in many countries, has collected the questions most frequently asked, and provides authoritative answers. In this book he has avoided the classical textbook presentation. He has chosen a framework which allows the user to go straight to the question he has in mind; there he will find a comprehensive answer, with ample cross-referencing to related problems.

The book is divided into two main parts: Case-finding, with 13 and Chemotherapy, with 40 questions and answers that between them cover a vast range of practical information. It includes a review of the relative merits of different diagnostic techniques, a critical assessment of case-finding policies, an analysis of the various drug regimens, especially short-course chemotherapy, and discussions of such matters as to whether it is necessary to isolate newly detected patients, to do pre-treatment drug-sensitivity tests, or to follow up patients after completion of chemotherapy; it ends with an account of the principles underlying controlled chemotherapy trials.

The book is addressed to all tuberculosis workers in key positions and to those who teach about tuberculosis control and it provides guidance to voluntary agencies and nongovernmental organizations concerned with tuberculosis control. Particular attention has been paid to the needs of developing countries, where more than three-quarters of the world's tuberculosis problem is concentrated. ▭

The primary health worker, revised edition, World Health Organization, 1980, Pages 346, Price: Sw. fr. 12.-

The 1978 Declaration of Alma-Ata states unequivocally that primary health care is the key to the attainment of a level of health that will permit people to lead a socially and economically productive life. Only a few countries, however, have been successful in developing a network for the delivery of health services that effectively covers the majority of the population. Among the features common to the different successful national schemes is the use of the "primary health worker", who is usually a villager selected by the community. Trained locally by the health services, he or she is responsible under their supervision for health promotion and for aspects of preventive and curative work.

WHO has now published this revised edition of the working guide for primary health workers and guidelines for their training that was first issued as an experimental manual in 1977. Intended as a practical tool to be used at the peripheral level of health services it shows, what the primary health workers can do, and how they can learn, about such matters as communicable diseases, maternal care, child health and nutrition, accidents, a variety of other complaints and conditions, village and home sanitation, and aspects of community development. There is also a list of common medicines, with notes on how to give them and how much to give, and basic instructions on how to give an injection, bandage a wound, take a pulse, and so on. The training guidelines show how to make learning at once interesting and effective. The manual may be used as it stands in many a situations and is really meant to be adapted to the conditions encountered in different countries or communities. ▭

Penicillin*: How to minimise allergic reactions?

The apparent increase in the incidence of penicillin allergic reactions is proportionate to the production and consumption of this antibiotic.

Following steps will be helpful in minimising allergic reactions:

1. Establish a clinical need for penicillin therapy.

2. Select proper penicillin preparation for the clinical conditions, e.g.;

- Benzathine penicillin for secondary prevention of rheumatic fever and treatment of syphilis;
- Procaine penicillin for gonorrhoea;
- Benzylpenicillin for acute infections caused by organisms sensitive to it; and
- Streptopenicillin for *Streptococcus viridans.*

3. Obtain a careful history from the patient regarding:

- Previous reactivity to penicillin products, type of reaction, if any;
- Penicillin handler or not;
- Previous penicillin therapy (possible only with intelligent patients) including estimated last dose; route of administration and duration, amount received and form of penicillin;
- Any reaction to common foods likely to contain various amount of penicillin: milk, ice cream, chicken, beer;
- Allergic diseases like rhinitis, asthma, eczema, contact dermatitis and urticaria;
- Family history of allergy; and
- Interdigital fungal infection and fungal superinfection due to prolonged antibiotic usage.

4. If there is no history of prior reactivity to penicillin products, perform skin test (left to the discretion of physician).

Scratch tests with PEN G or PPL: A drop of each skin test reagent is placed on the forcarm from 1 ml syringe.

Several 1 cm scratches through the drop are performed using the 26 g syringe needle. If there is no induration at 5 minutes, an intradermal test may be placed. If the scratch test is positive at 10 minutes, it should be read again at 15 minutes as some irritative reactions appear early and disappear by 15 to 20 minutes.

Any induration around the scratch marks which persists more than 20 minutes is considered positive. If any doubt exists, the more definitive intradermal skin test should be employed.

Intradermal test: A 3mm intradermal bleb is raised in duplicate on the forearm; it must be remembered that subcutaneous tests are invalid. The test requires only 0.02 to 0.04 ml reagents.

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* This write-up is based on a publication from Hindustan Antibiotics Ltd., Pimpri, Pune-411018.

At 15 to 20 minutes, the diameter of induration is measured. If greater than 5 mm, the test is positive-regardless of the presence or absence of erythema. If the duplicate skin tests for each reagent do not agree, that skin test should be repeated. Buffered saline solution may be used as control.

Application of tests :

- Administer scratch test with penicilloyl-polylysine;
- Administer intradermal test with penicilloyl-polylysine;
- Administer scratch test (15 min) with 1 drop of solution containing 10,000 units/ml on forearm;
- Administer intradermal test (15 min) with 0.02 ml of solution containing 100 units/ml; and
- Proceed with penicillin administration as outlined in Table 1.

Record blood pressure, pulse and respiration at frequent (5 min) intervals and have "Emergency Kit" and antianaphylactic equipment always at hand (Table 2).

Immediately begin continuous therapy with intravenous penicillin G if necessary.

5. If there is a history of previous reaction:

- Scratch test with both reagents should be performed before an intradermal test is placed. If positive, an intradermal test should not be performed. (*Caution*: Recent antihistamine therapy especially hydroxyzine—not moderate corticosteroids, <60 mg prednisolone—may blunt or totally abate wheal and flare type of skin tests).

TABLE 1

Penicillin concentration (units/ml)	*Milliliters injected each 15 min.*	*Units injected subcutaneously*
100	0.05	5
	0.1	10
	0.2	20
	0.4	40
	0.8	80
1,000	0.15	150
	0.3	300
	0.6	600
	1.0	1,000
10,000	0.2	2,000
	0.4	4,000
	0.8	8,000
100,000	0.15	15,000
	0.3	30,000
	0.6	60,000
	1.0	100,000
1,000,000	0.2	200,000
	0.4	400,000
	0.8	800,000

6. If either of the skin tests is positive, any penicillin or cephalosporin drug is contraindicated. Clinical desensitization to penicillin by a physician experienced in this technique is advocated after patient is hospitalised.

7. If both skin tests are negative, the patient may be given penicillins or cephalosporins with small risks (<1%) of anaphylaxis or acute urticaria. Nevertheless, physician supervision of the administration of the first dose is strongly recommended, especially in patients with convincing histories of prior allergic reactions. The patient should be kept fully informed of the risk of reaction in the

case of negative skin tests, and the possibility of resensitization by subsequent doses of penicillin. All patients with impressive histories should be encouraged to demand skin testing prior to every subsequent course of penicillin therapy.

8. While using penicillin for therapeutic purposes, it is advisable to use fresh solutions of recent batches because allergenic determinants accumulate in aqueous solution of benzylpenicillin stored at room temperature or in refrigerator when pH of the unbuffered solution falls.

Use noradrenaline or metraminol in 5% glucose.

- If associated with cyanosis: Use oxygen.

- If bronchospasm not responding to injection adrenaline, use:

(*i*) Chlorpheniramine (10 mg/ml) 1-2 ml *im* or equivalent dose of other antihistamine agents.

(*ii*) Aminophylline: 250 to 500 mg by *im* or *iv* route, well diluted and administered slowly over a period of about 10 minutes.

TABLE 2: Antianaphylactic equipment

Basic supplies *Drugs for injection (Emergency kit)*	Syringess, hypodermic needles Epinephrine (aueous 1:1,000) and Ephedrine, *im* Chlorpheniramine (10 mg/ml)	Alcohol sponges Metaraminol, (Aramine Metaraminol) or phenylephrine, Levarterenol (Levophed), Aminophylline Corticosteroids
Equipment for intravenous infusion and tracheostomy	Tournique, venous cutdown equipment, 5% glucose infusion bottles with transfusion set Sphygmomanometer	Stethoscope, Oxygen tank, with mask or intranasal tube, or bag and valve epuipment, Endotracheal tube

9. Traces of penicillin in improperly washed syringes may contaminate injection i.e., products from the degradation of the penicillin molecules will have immunosensitising molecules. Therefore, use of disposable syringes is advocated.

10. In the event of anaphylactoid reaction, drugs in following order (Table 2) from antianaphylactic equipment should be used:

- Bronchospasm: Injection adrenaline (1 : 1000) 0.3 to 0.5 ml *im*.

- If associated with hypotension:

(*iii*) Corticosteroid: Dexamethasone sodium phosphate (Decadron phosphate injection, 4 mg/ml) can be given directly from the vial without mixing or dilution. It should be administered by *iv* drip or slow *iv* injection for the initial dose and for subsequent doses while the patient is in shock. The *iv* dose is 4 to 20 mg depending on the severity of the condition, repeated until adequate response is discernible. Total daily dose need not exceed 80 mg even in severe conditions.

Judicious use of antianaphylactic drugs can reduce the fatality rate to a considerable extent.

DRUG INDUSTRY

General News

Licencing capacity rules liberalised

A Cabinet Committee on Exports presided over by Mrs. Indira Gandhi, has decided to liberalise the licencing capacity regulations and permissible royalty rates on imported technology to all exporting units including the MRTP companies. This decision is based on the recommendations of Tandon Committee which was asked to suggest measures for stepping up the exports.

The industrial units can now produce beyond their licenced capacity, without limit, to the extent they export. The present five per cent restriction on the royalty payable on technology imports has also been removed on the export sales. However, the committee has turned down the recommendation for raising the asset limit of the large industrial houses from Rs. 20 crore to Rs. 50 crore.

Now no licence is required to make variations of a product if the export order so requires. Technology imports which involve lumpsum payments will be considered more liberally.

Shortage of many drug formulations feared

It is reported that over 1000 life saving drug formulations marketed by different companies will be out of the market soon if the recently proposed guidelines of the Union Government about harmful combinations are implemented. A sub-committee of the Union Cabinet after examining 34 categories of drug combinations has felt that there is no therapeutic rationale in marketing of 23 of them (*see* This bulletin **3,** No. 9, p 301).

The drug controller has informed the industry associations that 16 such categories of combinations will be immediately disallowed and the remaining 7 categories withdrawn in a phased manner. These 16 categories are estimated to have more than 1000 formulations of various drug companies. The industry was to give their views on this proposal of Central Drug Control Authorities by 30th September 1980.

Drug industry seeks time for formulations weeding out

It is reported that major associations of drug industry have asked the Union Government to grant six months time to furnish details, regarding formulations, proposed to be banned (*See*, This bulletin, **3,** No. 9, p 301). The Government had asked the industry associations to send their comments by 30th September on the withdrawl proposal.

According to industry sources, a complete withdrawl of all formulations covered under 16 categories of drug combinations will affect many formulations which have no proven harmful effects and are well accepted by patients and medical profession.

The industry is of the view that in case the Government finally decides to weed out the harmful or irrational drug combinations then the affected companies should be given a fresh licence for the manufacture of another formulation without delay.

Rs. 4.62 crore increase in medicines' export

According to an official report, India's export of medicines has registered an increase of Rs. 4.62 crore comprising basic drugs, Rs. 13.43 crore; finished formulations, Rs. 38.32 crore; ayurvedic and unani medicines, Rs. 1.01 crore; and homoeopathic drugs Rs. 20,000.

The basic drugs were sent mainly to W. Germany, Switzerland, Netherlands, UK, Italy, USA, Canada, Japan and USSR. Finished formulations were exported to Malaysia, Singapore, Nepal Kuwait, Saudi Arabia, Tanzania, Kenya etc. The export of medicinal castor oil was to USSR, France, USA, Japan and Holland.

Basic chemicals export up

Export of basic chemicals and its other allied items recorded a sharp rise of 43 per cent during April-July 1980, touching Rs. 73.31 crores as compared to Rs. 51.14 crores in the same period last year.

Drugs, pharmaceuticals and fine chemicals export during the period went up to Rs. 32.18 crores as against Rs. 19.62 crore in the same period of the preceding year. Similarly, export of other items showed an encouraging trends.

Sarabhai acquires Suhrid-Geigy share holding

Sarabhai, the Ahmedabad based pharmaceutical company has reportedly acquired the foreign shareholding of Suhrid Geigy by acquiring 47.5 per cent of the paid-up capital of Suhrid-Geigy from the foreign collaborators, Ciba-Geigy. A new compay called Ambalal Sarabhai Enterprises has been established to integrate various small Sarabhai Enterprises and to incorporate various undertakings and business promoted by them including the Suhrid-Geigy business. Suhrid-Geigy is engaged in the manufacture of industrial chemicals, optical whiteners, dyes, intermediates, drugs and pharmaceuticals. The new enterprise has also made negotiations to purchase the remaining 52.5 per cent shares so as to completely merge Suhrid-Geigy with Ambalal Sarabhai Enterprises.

Vitamin C production to be stepped up

The production of vitamin C, a bulk drug used in the manufacture of several formulations, will be stepped up substantially in the current year in view of the sharp rise in demand. The estimated demand for this vitamin in 1980-81, is expected to be 965 tonnes against a requirement of 840 tonnes in 1979-80.

Jayant Vitamins the leading manufacturer of this drug is expected to run at the full licenced capacity of 500 tonnes this year. Last year, it produced only 50 per cent of its capacity. Sarabhai Chemicals, another manufacturer of the drug, has been producing much in excess of the licenced capacity of 240 tonnes. The production by Hindustan Antibiotics Ltd., the third manufacturer, has been very small so far, though it is licenced to produce 125 tonnes. This company is expected to increase the production this year so as to achieve the targeted production.

Early decision on amidopyrine ban demanded

Use of amidopyrine—a controversial painkiller may soon be banned. This drug has already been banned in more than 20 countries and is known to produce deleterious side-effects including the destruction of white blood corpuscles. This finally leads to agranulocytosis.

The Drug Controller of India had notified as early as January 1979 asking formulators to withdraw amidopyrine in a phased manner, but no deadline was specified. Even now there are more than 30 formulations containing this drug. Sandoz, a multinational is marketing cibalgin compositum and spasmo cibalgin and Suhrid-Geigy has esgipyrin which is also a widely selling analgesic.

Sandoz, who had indicated their willingness to substitute amidopyrin by optalidon P, moved an application for this substitution. But the Ministry for Petroleum and Chemicals turned it down on the plea that this calls for a fresh licence and finally 'closed' the Sandoz application. Even after all such reports of toxicity the drugs containing amidopyrine are being marketed because drug controller as well as Ministry of Petroleum and Chemicals have not taken any concrete action.

New WHO chief for south-east Asia region

Dr. U. Ko Ko of Burma has been nominated Regional Director of the World Health Organisation's south-east Asia region. Dr. Ko's nomination is to be confirmed by the WHO executive board. Dr. Ko who succeeds Dr. Y.T.H. Gunaratne had joined WHO in 1969 in community health services.

$ 11,667 million worth of drugs exported by US

According to the newly released "Current Industrial Report on Pharmaceutical Preparations, Except Biologicals" by US Bureau of Census the total shipments by manufacturers were $11,667,000, 000 worth of pharmaceutical non-biologicals. Following table gives the categorywise shipment (non-biologicals) in detail:—

Preparations for		*Shipment (in million)*
CNS and sense organs	—	2756.1
Cardiovascular system	—	969.3
Digestive or genito-urinary systems	—	1177.6
Neoplasms, endocrine systems, metabolic diseases	—	1002.4
Parasitic and infective diseases	—	1482.1
Respiratory system	—	1053.0
Skin	—	714.6
Vitamin, nutrient and hematinic preparations	—	1689.7

PMA Newsletters, **22**, 1 (29 Sept. 80)

Pharmaceutical innovations stifled by over regulations: OECD report

Excessive Government controls during the last 15 years on the operations and structure of the pharmaceutical industry have led to a situation in which innovations of crucial importance have suffered, according to a report published by the Organisation for Economic Cooperation and Development.

The pharmaceutical industry basically survives by the success of innovations, says the report, and the gross effect of changes in environment in which it operates erodes its capacity and enthusiasm for innovation. In USA, the progress in new research since 1960 is very slow because of the fact that a substantial portion of the research funds has to be devoted for ensuring greater safety and efficacy of products. The report says that industry in US has the greatest pressure of Government regulations and cost of innovation perhaps the highest. The industry in US has fallen behind Europe and Japan in production growth, R & D expenditure, exports, and patent registration. Of course, the trend towards Government control and innovation costs is universal and pharmaceutical development is equally hampered in every country.

About the time spent on drug development, the report says, that regulations on safety, efficacy, GLP and GMP have extended the time required to gain marketing approval between 7 and 12 years in US. Moreover, the often required requirement to duplicate testing procedures for obtaining registration in other countries leads to further delay in marketing.

Rising inputs and other costs have further reduced the profit and investment incentive. Expenditure has increased by over 1000 per cent since 1970, due to inflation, expensive research and manufacturing processes, longer introduction time etc. This has led to a situation where industry wants to go for short term profitability. Though more fundamental drug research is needed, industry is diversifying increasingly. The report finally calls for Governments to assess the long term implications of regulations and to reduce introduction times.

Scrip, No. **524,** 2 (17 Sept. 80)

Company Reports

Boehringer-Knoll to increase chloramphenicol capacity

The expansion programmes of Boehringer-Knoll envisage monthly increase of 5 tonnes in chloramphenicol capacity by early 1981. The company has also received letters of intent for the manufacture of α-methyl dopa, theophylline and aminophylline. These projects are proposed to be undertaken at Patalganga, a backward district of Maharashtra. The technology for these projects will be supplied by W. Germany.

CE Fulford to go public

CE Fulford (India) Pvt Ltd a wholly owned subsidiary of CE Fulford Ltd of UK has decided to become a public limited company. The company proposes to raise a capital of Rs. 24 lakh through issuance of 2.4 lakh equity shares at a par value of Rs 10 each share. Of these 2.4 lakh shares, 1.6 lakh will be for the public financial institutions and 10,000 will go to company employees in accordance with the New Drug Policy. This issue will bring down the foreign holding from 100% to 40%.

IDL Chemicals raises dividend

The Board of Directors of IDL Ltd, Bombay has decided to increase the dividend from 6 per cent to 8 per cent for the year ended June, 1980. The turnover declined from Rs 27.74 crore to Rs 27.62 crore but the gross profit increased from Rs 3.29 crore to Rs 3.61 crore.

The explosive division output has declined because of lockout but pharmaceutical division at Bangalore is doing well. The company has signed an agreement with Astra Ltd for the manufacture of bulk drugs and formulations.

Nicholas Lab sales, profits up

Nicholas Laboratories India has recommended a final dividend of 12 per cent for the year ended June 1980. With an already declared interim dividend of six per cent the total dividend comes to 18 per cent. The company achieved a sales of Rs 8.94 crore this year compared to Rs 7.04 crore for the preceding year. The gross profit increased from Rs 92.97 lakhs to Rs 1.06 crore. The net profit increased to Rs. 28.91 lakhs from Rs. 18.06 lakhs for the year before.

Punjab to set up 4 more glucose units

To meet the growing requirements of the state, Punjab Government has decided to set up 4 glucose plants in addition to the existing one. The units will be located at Amritsar, Faridkot, Jullundur and Ludhiana.

Research and Development

Drug for penicillin resistant gonorrhoea developed

Lederle Laboratories have synthesized a drug capable of killing the penicillin resistant strains of gonorrhoea. The drug, piperacillin, is without the side effects usually associated with other antibiotics.

Antiviral substance from breast milk

A naturally occurring substance present in breast milk has been found to be helpful in preventing infantile diarrhoea caused by rotavirus. A study being conducted at the St. Thomas hospital London has shown that breast fed infants suffer less often from rotavirus infection than did bottle fed infants.

Human milk might, therefore, contain some substance which specifically acted against the rotavirus and efforts are underway to identify it, so as to exploit its usefulness as an antiviral drug.

Pharmaceutical J., **225**, 286 (13 Sept. 80)

Cimetidine interacts with tetracycline

According to the preliminary results of a study, lowering of gastric acidity by cimetidine could have important effects on the bioavailability of other drugs given concurrently. A reduced absorption of tetracycline is observed when given with cimetidine. The results indicate that co-administration of cimetidine substantially reduces the absorption of tetracycline from capsules but has insignificant effect on absorption from solution. It is inferred that cimetidine does not affect absorption of the antibiotic but the lowered gastric acidity reduces the dissolution of capsules. This interaction could lead to therapeutic failure according to the study.

Lancet, 536, II (1980)

Interferon to be produced by fermenting yeast

National Patent of USA has signed an agreement with Collaborative Research to develop interferon using an alternative recombinant DNA technique based on the genetic engineering of yeast. According to Mr. Jarome Feldman, the President of National Patent, because of their past experience with yeast fermentation, the present process will have an increased safety and reduced cost. The ineffectiveness of the interferon produced from *E. coli* may be because of suspected inability of the organism's genes to attach the appropriate sugar moieties to the interferon molecule. Unlike bacterial cells, yeast genes produce no endotoxins and are easier and cheaper to grow.

Scrip, No. **522,** 11 (10 Sept. 80)

Synthetic cannabinoids have advantages over natural product

Of the over 20 cannabinoids isolated from *Cannabis sativa*, △-9-tetrahydrocannabinol has been found to be the most active one. Many synthetic derivatives of △-9-THC have been prepared. Cannabinoids can be used for the following therapeutic categories:

Analgesics: Some cannabinoids seem to produce analgesia but only at a dose which also produces unwanted side effects.

Antianxiety agents: Although marihuana smokers claim some relief, no study on high anxiety patients has been conducted. It is difficult to replace benzodiazepines in this category of patients, since they have least side effects.

Antiasthmatics: Some studies point out that △-9-THC reduces airway resistance and increases conductance. Side effects like drug related bronchospasm, euphoria and sedation are observed.

Anticonvulsants: Despite some controversy, cannabinol and cannabidiol have been claimed to have anticonvulsant properties, when given in high doses.

Antiemetics: Nabilone, the synthetic cannabinoid has been found to be effective against *cis*-platinum and produces minimal side effects.

Glaucoma therapy: Marihuana reduces intraocular pressure by about 30% in glaucoma patents. Though its use is not well established, preliminary results have shown good promise.

The use of cannabinoids in other indications such as antihypertensives, antitumour and anti-inflammatory agents is not well established so far. Synthetic cannabinoid derivatives show a better organ specificity and more reproducible pharmacological effects. Thus, it gives them a clear advantage over △-9-THC as therapeutic agents.

Inpharma, No. **253,** 3 (6 Sept 80)

Folate may reduce cervical cancer risk

Folic acid treatment may help to reduce the risk of cervical cancer in women taking combination oral contraceptives. Significant improvement in mild to moderate cervical dysplasia was observed in women given 10 mg of folate daily for 3 months.

Although there is no epidemiological evidence of an increased risk of cervical cancer with oral contraceptives, it is feared that cervical dysplasia progresses to carcinoma of the cervix in some women and there is preliminary evidence that use of oral contraceptives hastens this process. A study spread over five years in which 47 women have been evaluated, folate had a substantial beneficial effect on the cervical epithelium. The amount of dysplasia shown by Papanicolaou smear decreased among women given folate, but did not change in women on placebo. In some subjects neoplasia completely disappeared. No women on folate developed carcinoma *in situ* during the follow up studies.

J. American Med. Assoc. **244,** 633 (15 Aug 80)

Valium, the maximum prescribed drug in US

According to certain reports Valium tablets (Diazepam, Roche), were at the top in number of prescriptions written. Tagamet (Cimetidine, SK&F) had the highest sales among the drugs. The first ten drugs arranged according to number of prescriptions written are: Valium, Dyazide caps, Lesix tabs, Tylenol tabs, Lanoxin tabs, Aldomet tabs, Darvocet-N tabs, Tagamet tabs, Dalmane caps and Inderal tabs.

The first ten drugs listed saleswise are: Tagamet, Valium tabs, Dyazide caps, Lasix tabs, Motrin tabs, Aldomet tabs, Inderal tabs, Keflex Pulvules, Tylenol and slow K tabs.

Scrip, No. **522,** 11 (10 Sept. 80)

REGULATORY NEWS

Guidelines issued for the revision of essential drugs' prices

The Union Cabinet has approved the following guidelines for the revision of drug prices:

1. Leader prices for categories I and II formulations including non-conforming packs will be worked out on the basis of 40% and 55% marks-up respectively;
2. The prices of non-conforming packs under categories I and II will be allowed to be increased to the ceiling level of leader prices;
3. Leader prices for category III formulations will be fixed on a 100 per cent mark-up basis. This will cover single ingredient as well as multiple ingredient compositions; and
4. In regard to non-conforming packs of category III, which have no leader price, an ad-hoc mark-up of 60 per cent will be allowed which may be readjusted in due course on the basis of a study of the overall profitability of each company. (This lower mark-up will also act as a disincentive to the marketing of non-conforming packs)

The following are the new estimated prices for some drug formulations, also showing the extent of increase or decrease in relation to the current rates:

Analgin tablets	—	Rs. 1.73 per pack, a decrease of ten paise
Aspirin tablets	—	Rs. 0.23 per pack, an increase of 5 paise for 10 tablets
Chloromycetin capsules	—	Rs. 4.98, increase of 83 paise per strip
Tetracycline capsules	—	Rs. 4.21, decrease of 58 paise per strip
Streptomycin sulphate-injection (1 gm vial)	—	Rs. 1.62, increase of 43 paise per vial
Benzyl penicillin sodium	—	Rs. 1.19, increase of 14 paise per vial
Enteroquinol tablets	—	Rs. 0.92, increase of 2 paise per strip
Dapsone tablets	—	Rs. 0.12, increase of 1 paise per ten tablets
Insulin injection (40 units/ml)	—	Rs. 10.57, decrease of 53 paise per vial
Insulin zinc suspension leute (40 units)	—	Rs. 10.57, decrease of Rs. 1.21 per vial
Furamide tablets	—	Rs. 5.43, increase of 9 paise per strip
Brufen tablets	—	Rs. 6.06, increase of 73 paise per strip
Roscillin capsules	—	Rs. 5.50, decrease of 68 paise per vial
Wysolone tablets	—	Rs. 2.49, increase of 34 paise per strip
Complamina tablets	—	Rs. 1.42 decrease of 83 paise per strip
Morphine injection	—	Rs. 0.69, increase of 20 paise per ampoule
Codopyrin tablets	—	Rs. 2.47, increase of Rs. 1.19 per strip
Raverin injection	—	Rs. 3.81, decrease of Rs. 2.54 per vial

Restinon tablets — Rs. 1.36, increase of 13 paise per strip

Albucid eye drops (20%) — Rs. 3.47, decrease of 25 paise per bottle

Lignocaine (2%) — Rs. 1.07, decrease of 1 paise per ampoule

Dextrose injection (5%) — Rs. 10.58, increase of Rs. 2.43 per bottle

The prices of these selected drug formulations are indicatory at present, because the Bureau of Industrial Costs and Prices has still to work out the exact revised prices. Moreover, these figures do not include the impact of the recent increase in the prices of petroleum and petroleum related products.

Distribution curbs on gentamycin sulphate waived off

The Union Ministry of Petroleum, Chemicals and Fertilizers has removed supply controls on gentamycin sulphate, a broad spectrum antibiotic. It is a canalised item under the import policy for the current year. Therefore, it is being distributed to actual users by CPC. With the removal of distribution of controls, actual users have not to go for registration and other requirements. This decision has been taken in view of the existing stock of Gentamycin with Hindustan Antibiotics Ltd. and their expected production during 1980-81.

Chloroquine formulations' export permitted

Under a public notice issued by the Chief Controller of Imports and Exports, the export of chloroquine phosphate formulations manufactured from indigenous bulk drug has been allowed subject to the condition that the quantity of bulk drug so used is replenished by imports within a period of six months from the date of exports.

At present the export of such formulations is allowed under OGL-3 only against import of bulk drug (chloroquine phosphate) under advance licence to the extent of f. o. b. value indicated in the licence.

Now the licencing authorities will allow export by issuing an import licence to the exporter on his furnishing a bond undertaking to import chloroquine phosphate for c. i. f. value equal to 30 per cent of the f. o. b. value of the exported formulations. The bond should be supported by a bank guarantee for an amount equal to 15 per cent of the f.o.b. value of the product to be exported. If the exporter fails to import the material within the stipulated period the bank guarantee will be liable for forfeiture.

Excise to replace ST on drugs

At the two-day conference of the Chief Ministers held in New Delhi recently, it has been decided that sales tax on 29 life saving drugs listed as such by Hathi Committee should be replaced by additional excise duties. Phasing out of octroi duty was also agreed upon. Initially the abolition should be in the towns having a population of two lakhs and less and could be progressively extended to bigger towns.

Propranolol HCl packages to carry a warning

Drug Controller of India has issued warning about the concurrent use of verapamil or clonidine with beta-blockers.

Some reports of low incidence of skin rashes or dry eyes associated with the use of all beta-blockers have been observed. These mild side-effects are not serious and have been reversed on discontinuance of the drug. The authorities want that following warning should be carried in the package insert/promotional literature on the drug:

1. *Under contra-indications/Warning:*

"Propranolol should not be used with verapamil/clonidine and neither drug should be administered within several days of discontinuing the other."

2. *Under adverse reactions:*

"There have been reports of skin rashes and/or dry eyes associated with the use of beta-adrenergic blocking drugs. The reported incidence is small and in most cases the symptoms have disappeared when treatment was withdrawn".

Fresh advice on smallpox vaccination

British Joint Committee on Vaccination and Immunisation has recommended that the following categories of workers be vaccinated against smallpox: 1. Investigators and staff working on or associated with smallpox virus. 2. Staff manning a hospital looking after suspected smallpox infected cases.

Vaccination could also be offered to families of those included in 1 & 2 above, and those engaged in the manufacture of vaccine or who perform vaccination.

However, World Health Organisation has notified that world is now free of smallpox, hence, there is no need of vaccination.

Pharmaceutical J., **225,** 247 (6 Sept. 80)

Ban proposed on food packages containing acrylonitrile residues

The Canadian Health Protection Branch has proposed to prohibit the sale of any food in a package that may yield to its contents, any amount of acrylonitrile.

A survey of the food packaged in plastic containers has revealed the presence of acrylonitrile in some of the foods sampled. Analysis of the containers showed them to be made from acrylonitrile copolymers containing residual acrylonitrile. Acrylonitrile has been found to be carcinogenic in the test animals in a toxicity study using rats. Based upon the results of this and other studies, it is presumed that acrylonitrile could also be carcinogenic to humans.

International Drug Regulatory Monitor, No. **88,** 26 (Sept. 80)

Bill to legalise heroine use introduced in US Congress

A bill calling for amendment in Controlled Substances Act to authorize the use of heroine for terminally ill cancer patients has been introduced in US Congress.

Heroine has been found to be a safe and effective painkiller and there is no reason to deny it to doctors for their dying patients. Of course, the concern for the patient must be weighed against fears that its availability may increase its already widespread abuse.

PMA Newsletter, No. **35,** 3 (8 Sept. 80)

Many drugs ordered to be withdrawn from Japanese market

The Pharmaceutical Affairs Bureau of the Japanese Ministry of Health and Welfare in its 17th drug efficacy review has found that 67 single ingredient drugs and 3 combination drugs have no evidence of availability. These have been ordered to be withdrawn from the market.

These products cover the seven therapeutic categories, *viz.*; (a) Agents relating to blood; (b) Psychotropic drugs; (c) Dermatological agents; (d) Cardiovascular drugs; (e) Analgesics; (f) Dental and oral cavity drugs; (g) Ophthalmic and otorhinological drugs and; (h) Hormones.

The withdrawn drugs consist of four products of reduced iron and one oral product of saccharated ferric oxide in category "a"; 37 products of adenosine, four products of heart preparations acting on cardiovascular system, one combination product of methoxydeserpidine/benzthiazide and one product of benzylhydrochlorothiazide/mebutamate in "d"; 13 injection products of horse chestnut seed extract in "e"; One product of sodium hypochlorite and two injection products of epidihydrocholesterin in "f"; one combination product of fradiomycin sulfate/colistin sulfate/hydrocortisone acetate in "g"; and two products of iodinated casein in the "h" category.

Japan Medical Gazette, **17,** 13 (20 Sept. 80)

INDUSTRIAL LICENCES AND LETTERS OF INTENT

ISSUED DURING JULY 1980

Sl. No.	Name and Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
	Licences				
1.	Bengal Immunity Co. Ltd. 153, Lenin Saranee, Calcutta.	Calcutta	(*i*) Ascacid B. I. tablets 500 mg (*ii*) 15 formulations in the form of ointment, tablets and injections	—	New Article
2.	Bhartiya Agro-Industries Foundation, "Kamdhenu" Plot No. 2106, A/2, A/14, S. B. Marg, Bombay.	Manjari Haveli Teh. Ponna (Maharashtra)	Foot & Mouth disease vaccine	3.2 million quadrivalent doses (exist.) 8.2 ,, (after expn.)	Substantial Expansion
3.	Boehringer-Knoll Ltd., United India Building, Sir P. Mehta Road, Bombay.	Thana (Maharashtra)	Phenformin hydrochloride	1 tonne	New Article
4.	Calcutta Chemicals Co. Ltd. 35, Panditia Road, Calcutta.	Calcutta	Diazepam tablets (5 mg & 10 mg)	100 lakh nos	New Article
5.	Ciba-Geigy of India Ltd., 14-J, Tata Road, Bombay.	Santa Monica Distt. Corlim Khas (Goa)	(*i*) Hydrochloric acid (33%) (*ii*) Methyl chloride (as by products from the effluent streams at Santa Monica Plant)	1500 tonnes 200 ,,	New Article
6.	Indian Drugs & Pharmaceuticals Ltd., N-12, South Extension, Part-I, Ring Road, New Delhi.	Gurgaon (Haryana)	(*i*) Sulphaphenazole tablets (*ii*) Sulphamethoxazol-trimethoprim tablets	Sulphaphenazole 78,750 kgs Sulphamethoxazol 4,200 kgs Trimethoprim 40 kgs	New Article

Contd.

Sl. No.	Name and address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
			(*iii*) Erythromycin estolate tablets	Erythromycin estolate 450 kgs	
			(*iv*) Erythromycin stearate tablets	Erythromycin stearate 4,813 kgs	
			(*v*) Sulphadimidine-bolus	Sulphadimidine 26, 250 kgs	
			(*vi*) Sulphadimidine-bolus	Sulphadimidine 26, 250 kgs	
			(*vii*) Potassium penicillin sulpha dimidine tablets	Penicillin 1,562 kgs Sulphadimidine 5,250 kgs	
7.	McGaw-Ravindra Laboratories (India) Ltd., Amraiwadi Road, Ahmedabad.	Ahmedabad	(*i*) Transfusion solution in bottles etc.	90 lakh nos	Substantial Expansion
			(*ii*) Disposable plastic sets etc.	30 ,,	
			(*iii*) Solutions in vials etc.	30 ,,	
			(*iv*) Sterile tubes & catheters etc.	9 ,,	
			(*v*) Miscellaneous plastic items	9 ,,	
8.	Suhrid Geigy Ltd., 'Shahibag House', Shahibag, Ahmedabad.	Ranoli Distt. Baroda	Imipramine & its salts	3000 kgs. (after expn.)	Substantial Expansion
9.	Unichem Laboratories Ltd., S. V. Road, Jogeshwari (West), Bombay.	Roha, Distt. Colaba, (Maharashtra)	Metronidazole	6 tonnes (exist.) 24 ,, (after expn.)	Substantial Expansion
10.	Unique Chemicals, 83 B and C, Dr. Annie Besant Road, Worli, Bombay.	Ankleshwar (Gujarat)	(*i*) Pheniramine maleate (*ii*) Chlorpheniramine maleate	10 tonnes	New Article
			(*iii*) Disodium cromoglycate	1 ,,	
			(*iv*) Chloramphenicol powder	25 ,,	
			(*v*) Chloramphenicol palmitate	15 ,,	

Sl. No.	Name and Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type of Licence
	Letters of Intent				
1.	Abbott Laboratories (India) Pvt. Ltd., Jehangir Building 133, Mahatma Gandhi Road, Fort, Bombay.	Roha (Maharashtra)	(*i*) Diothyl malonate	150 tonnes	New Article
			(*ii*) Pentothal sodium	5 ,,	
			(*iii*) Nembutal sodium	5 ,,	
			(*iv*) Motformin	50 ,,	
			(*v*) Chloroquin phosphate	30 ,,	
			(*vi*) Substituted melonic esters (except N-butyl malonate)	125 ,,	
2.	Dr. Ramesh C. Jain, C-10, CC Colony, (Opp. Rana Pratap Bagh) Delhi.	Bhiwadi Alwar (Rajasthan)	Ampicillin trihydrate	20 tonnes	New Unit
3.	Indian Drugs & Pharmaceuticals Ltd., Post Box No. 3816, New Delhi.	Rangareddy, Hyderabad	(*i*) Sulphadimathexine	40 million tabs.	New Unit
			(*ii*) Suphamethizole	10 ,, ,,	
			(*iii*) Sodium PAS plus INH	20000 kgs	
			(*iv*) Haematinin syrup	100 k.l.	
			(*v*) Haematinic capsule	50 million capsules	
4.	Kerala State Drugs & Pharmaceuticals Ltd., Kalavoor, Alleppey, Kerala.	Ambalapuzha Alleppey (Kerala)	(*i*) Ascorbic acid tablets IP ascorbic acid	5500 kg	Substantial Expansion
			(*ii*) Aspirin IP acetylsalicyclic acid	60000 ,,	
			(*iii*) APC IP acetylsalicyclic acid	2000 ,,	
			(*iv*) Phenacetin	1500 ,,	
			(*v*) Caffeine	300 ,,	
5.	Sudha Drugs & Chemicals (India) Ltd., Kothi No. 26, Sector 9-A, Chandigarh.	Rajpura Distt. Patiala (Punjab)	Chloroquin salts	20 tonnes	New Unit

NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
1.	*Antianginal*			
	Nitroglycerin ointment	Nitro-Bid	Protea	Australia
2.	*Antibacterial*			
	Ciclacillin	Calthor	Ayerst	UK
	Tetroxoprim + sulfadiazine	Tibirox	Roche	Switzerland
3.	*Anticonvulsant*			
	Valproic acid	Depakene	Abbott	Philippines
4.	*Antidepressant*			
	Trazodone	Molipaxin	Roussel	UK
5.	*Antihyperlipidemic*			
	Probucol	Lursell	Lepetit	Switzerland
6.	*Antihypertensive*			
	Minoxidil	Loniten	Upjohn	Australia
7.	*Anti-inflammatory*			
	Piroxicam	Feldene	Pfizer	Hongkong/ Malaysia/ Singapore/ S. Korea
8.	*Antineoplastic*			
	Lomustine	CeeNU	Bristol	Australia
9.	*Antiparasitic*			
	Secnidazole	Flagentyl	Rhone-Poulenc	France/Mexico/ Portugal
10.	*Antipsychotic*			
	Fluspirilene	Imap	Janssen	Philippines
	Loxapine	Loxapac	Lederle	Australia

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
11.	*Antiulcer agent*			
	Sucralfate	Ulcermin	Chugai	W. Germany
12.	*β-Blocker/diuretic*			
	Atenolol + Chlorthalidone	Tenoretic	ICI	Switzerland
13.	*Bronchodilator*			
	Fenspiride	Pneumorel/	Servier	Philippines
14.	*Corticosteroid*			
	Betamethasone dipropionate + betamethasone sodium phosphate	Diprosan	Schering	Philippines
15.	*Diuretic*			
	Spironolactone	Spiroctan	MCP	UK
16.	*Estrogen*			
	Estradiol + estriol +norethindrone	Trisequens	Organon	UK
17.	*GI regulator*			
	Domperidone	Motilium	Janssen	Philippines
18.	*Local anaesthetic*			
	Etidocaine	Duranest	Astra	Australia
19.	*Mucolytic*			
	Domiodol	Mucolitico	Maggioni	Italy
20.	*Muscle relaxant*			
	Fazadinium bromide	Fazadon	Glaxo	Philippines
21.	*Narcotic analgesic*			
	Oxycodone	Endone	Endo	Australia
22.	*Schistosomicide*			
	Oxamniquine	Vancil	Pfizer	Puerto Rico
23.	*Topical antibiotic*			
	Erythromycin	Staticin	Westwood	USA

Contd.

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
24.	*Topical anti-inflammatory*			
	Benzydamine	Difflam	Carnegie	UK
25.	*Topical corticosteroid*			
	Clocortolone pivalate	Cloderm	Ortho	USA
26.	*Topical corticosteroid/antifungal*			
	Miconazole + hydrocortisone	Daktacort	Janssen	S. Africa
27.	*Topical corticosteroid/antimicrobial*			
	Econazole + triamcinolone	Pevisone	Cilag	Philippines
28.	*Vasodilator*			
	Flunarizine	Sibelium	Janssen	Philippines

BOOK REVIEW

Epidemiology and control of schistosomiasis

Report of a WHO Expert Committee. World Health Organization Technical Report Series, No. 643, 1980, Pages 65 Price: Sw. fr. 4-.

Despite many years' efforts to control schistosomiasis, the most recent estimate of the global prevalence is set at some 200 million cases. According to the WHO Expert Committee on the Epidemiology and Control of Schistosomiasis the population at risk in the endemic areas is increasing, because an increase in the number of water impoundments and irrigation canal systems help spread the disease, and the overall infection rate also appears to have increased. However, sufficiently important advances have been made in the past decade like control programmes involving an appropriate combination of chemotherapy, mollusciciding, basic sanitation and the supply of potable water at the village level, and continuing health education and socio-economic development.

The early part of the report presents a fairly detailed picture of the biology, ecology, and distribution of the parasites and their intermediate snail hosts and discusses the epidemiology of human infection (including epidemiological models and standard quantitative methods of determining both the intensity of infection and morbidity). Every group of experts on schistosomiasis convened by WHO since 1949 has stressed the imperative need for cooperation between the health administrations and other authorities when man-made water resources are planned and built in areas where schistosomiasis is endemic or might be introduced. But the present Committee, too, has had to express its concern at the apparent lack of interdisciplinary consultation at the planning stage and to reiterate that the economic returns from such resources may be jeopardized by the ensuing disease if the health aspects are not taken into account from the outset.

The Committee first reviews the progress of a number of antischistosomiasis programmes in Africa, Asia and Latin America, and considers the newer chemotherapeutic drugs and molluscides, as well as control of snails by environmental modification and the possibility of biological intervention. The drugs available today are far less toxic than those of even 15 years ago. Since the strategy of control by selective population chemotherapy depends on repeated use of drugs, the dosage for some of them may have to be reduced below the optimum clinical level for the individual treated patient in order to make them acceptable on a population basis. The properties of antischistosomals relevant to large-scale use are presented in a table. Similarly, the properties of available and candidate molluscicides are tabulated and discussed. Particular importance is attached to appropriate health education of the public and to active community participation in control work.

The Committee has emphasized that the combination of measures, chosen for an integrated approach to schistosomiasis control, must be adapted to the local circumstances. And therefore, factors influencing the choice of control methods and evaluation of control schemes have been discussed.

In its conclusions the Committee has pointed out that their are now enough ways, given sufficient political determination, for launching national schistosomiasis control programmes and suggests that in countries where the disease is endemic these programmes should be conducted within the health care delivery systems. □

DRAFT REPORT OF THE WORKING GROUP ON DRUGS AND PHARMACEUTICALS INDUSTRY*

A Working Group set up by the Union Government to prepare a report on the drugs and pharmaceuticals industry for the plan period 1979-80 to 1984-85 has submitted the draft for the consideration of Government and industry—public as well as private sector. The report, in addition to, reviewing the past performance of the drug industry and its present status has made demand projections for the plan period under consideration. The following is the text of the report:

Present Status of Industry:—The Drugs & Pharmaceuticals Industry in India has made steady and considerable progress during the last two decades. The present production covers a wide range of bulk drugs including antibiotics, sulfonamides, vitamins, steroids and synthetics, phytochemicals, biological products and sutures and catguts besides practically the entire range of formulations desired by the medical profession. The technology adopted for the production of different bulk drugs includes intricate and sophisticated fermentation technology, synthetic operations and extraction and purification of the active principles from natural products found in the animal and plant kingdom.

1. The overall production of drugs and pharmaceuticals during the last four years was as follows:—

Year	Bulk drugs (Rs. in Crores)	Formulations (Rs. in Crores)
1975-76	130	560
1976-77	150	700
1977-78	164	900
1978-79	200	1050
1979-80	220	1150

2. Indigenous production of bulk drugs meets the major portion of the needs of formulations produced in the country. However, sizeable quantities of bulk drugs are imported to augment indigenous production. The following are the figures of imports of bulk drugs into the country during the last four years:—

Year	Imports (CIF) (Rs. in Crores)
1975-76	39.3
1976-77	47.00
1977-78	84.00
1978-79	80.00
1979-80	80.00 (estimated).

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* Photocopies available on request from National Information Centre for Drugs & Pharmaceuticals.

3. The imports of finished formulations into the country are negligible.

4. The induction of the public sector has given a major thrust to the production within the country of bulk drugs which had to be imported earlier. However, all the sectors, namely, the public sector, the organised sector and the small scale have made sizeable contributions to the production of bulk drugs as well as formulations as can be seen from the table below:—

Year	No. of Units	Production of Bulk Drugs		Bulk Drug Consumed Indigenous/ Import %	Production of Formulations	
		Value Rs. in Million	% of Total		Value Rs. in Million	% of Total
1976-77						
1. Public Sector	2	480	33		470	7
2. Organised Sector	128	920	60		5330	76
3. Small Scale Sector about	2500	100	7		1200	17
		1500	100	65		
Imported Bulk Drugs (landed cost)		820		35	—	—
		2320		100	7000	100
1977-78						
1. Public Sector	2	470	29		530	6
2. Organised Sector	128	1050	64		6970	77
3. Small Scale Sector about	2800	120	7		1500	17
		1640	100	53	9000	100
Imported Bulk Drugs (landed cost)		1470		47		
		3110		100		
1978-79						
1. Public Sector	3	490	24.5		600	5.7
2. Organised Sector	140	1310	65.5		8000	76 2
3. Small Scale Sector about	3000	200	10.0		1900	18.1
		2000	100.0	57	10500	100.0
Imported Bulk drugs (landed cost)		1800		43		
Total		3500		100		

5. The industry has entered the export market also and increasing quantities of both bulk drugs and formulations are now being exported. The table below shows the export performance of the last few years in terms of value of exports of bulk drugs and formulations.

Year	Bulk Drug	Formulations
	(Rs. in Crores)	
1975-76	6.99	16.43
1976-77	8.11	17.12
1977-78	8.87	16.72
1978-79	9.50	21.00

6. The rapid development of the pharmaceutical industry has created a demand for indigenous manufacture of plant and machinery required for the industry, both for the manufacture of bulk drugs and intermediates and for the formulations. The indigenous availability of bulk drug manufacturing machinery includes the whole range like reaction vessels of various materials of construction such as stainless steel, glasslined, rubberlined, leadlined, plastic-coated, mild steel, glass, etc., low and medium pressure vessels, storage tanks of various materials and construction, transfer equipment such as pumps of various types, blowers, conveyors etc., vacuum arrangements such as steam ejectors, high vacuum pumps (water seal as well as oil seal), mass separation equipment like centrifuges, filter press, dust collectors, liquid/liquid extractors, distillation columns and crystallizers, thermal equipment such as tray dryers, fluidized bed dryers etc. as well as pipes, valves and fittings of various types and different material of construction. Service equipment such as step-down transformers, rectifiers, steam boilers, refrigerators, compressors, cooling towers, demineralised water plants, etc. are also abundantly available indigenously.

7. In the area of process control instruments, indicating instruments for pressure, temperature, pH, conductivity, flow of fluids and humidity are being fabricated. Laboratory instruments such as precision balance, photoelectric colorimeter, visible absorption & emission spectrophotometers, gas-liquid chromatographs, different types of calculation machines, thin-layer chromatographic instruments, etc. are also being manufactured indigenously.

8. The pharmaceutical processing and packing machinery manufactured now includes the whole range of equipment needed for the manufacture of granules, powders, tablets, etc. including ribbon blender, mass mixer (sigma blade type), granulator (oscillating, multimill, etc.) tray and fluid bed dryers, high speed rotary tablet-process with dies and punches upto 45 stations, coating pans, polishing drums, tablets and capsules counting machines, capsule filling, sealing and printing machines (both hand operated as well as semi-automatic machines), ointment filling and packing machines, semi-automatic ampoule filling and sealing machines, sterile and non-sterile powder filling machines, laminar flow hoods, semi-automatic bottle washing, filling, sealing and labelling machines for liquid preparations, strip packing machines for tablets & capsules, ampoule washing machines, packing and checking belts, ete.,

9. A large capacity for the production of absorbable as well as non-absorbable, plain as well as needled sutures from the intestines of sheeps and goats (for the absorbable sutures) as well as from silk, polyester and nylon has been established and the country is largely self-sufficient in this field. A large capacity for the manufacture of condoms and intra-uterine devices required for the family planning programmes has also been set up in the country.

10. The production of bulk drugs and their availability forms the backbone of the pharmaceutical industry in any country. Being conscious of this right from the very beginning, the industry over the years, has developed considerable technological competence in the production of a large number of bulk drugs. Barring a few bulk drugs, the technologies for most of the items, were, so to say, imported during 1950's. With a view to be self-sufficient in the production of bulk drugs, the industry has been able, in many cases, to assimilate, modify, update and improve upon the technologies which were originally imported. Of late, however, totally indigenous technologies have been developed for a number of products. In some of these cases the methods of manufacture are totally new and suited to Indian conditions.

11. The technological competence developed over the years has made several companies in the country confident of transferring technology to other units. A number of consultancy and project engineering and design firms have emerged which are able to offer technology with full project design and even manufacturing plants on a turn-key basis.

12. In the field of production of pharmaceutical formulations the country has made significant progress and is largely self-reliant in the production of a wide range of dosage forms. Thus the industry is manufacturing all types of tablets including coated, sustained release and multicoated ones, capsules including hard as well as soft gelatine, injectables including small volume as well as large volume transfusions, oral liquids including syrups, elixirs and solutions, ointments and creams, injectable dry powders, inhalers, etc.. Know-how for these formulations have been developed mostly by indigenous efforts. The industry is at the moment capable of transferring complete project designs and assistance for the setting up of manufacturing units on a turn-key basis.

Demand projections up to 1984-85 alongwith the year-wise phasing:— With a view to estimating the future demand for each drug, a drug by drug analysis of the past availability pattern has been carried out taking into consideration indigenous production and imports. This was to find out the trend of consumption of each important bulk drug in the country. This method gave a good insight into the pattern of consumption which was taken into consideration in arriving at the future demand estimates. Other factors such as degree of obsolescence, budget provision for investment in the public sector undertakings, outlays on public health schemes of the Govt. of India, were also taken into consideration and the figures have been finalised in consultation with the representatives of other Ministries including the Ministry of Health, and also the representatives of the major pharmaceutical associations so as to make the demand projections as realistic as possible. While identifying the list of bulk drugs for which projections were made, an A B C analysis of the value of the bulk drugs was made and the important ones having larger consumption in terms of quantity as well as value and also being of essential life-saving nature were selected for these projections. In the process, 126 bulk drugs were identified which would constitute about 90% of the total consumption of the bulk drugs in the country. In this document, drugs such as sera, vaccines as well as veterinary drugs have been excluded since, in the case of former, the Ministry of Health has a Standing Vaccine Board which is exclusively engaged in the projections of demand and capacity in respect of sera and vaccines and, in the case of the latter, the Animal Husbandry Commissioner of the Ministry of Food & Agriculture is entrusted with the demand projections. Also in terms of value the quantum of consumption of sera and vaccines as well as veterinary drugs would constitute only about 5% of the consumption of bulk drugs in the country. Annexure-I gives the demand projections of the 126 identified bulk drugs from 1979-80 to 1984-85. It also indicates the estimated rate of growth of requirement of these drugs,

Investment:—The requirement of bulk drugs by 1984-85 at current cost would work out to about Rs. 815 crores. At the current level of imports (nearly Rs. 80 crores CIF) the country has, more or less, reached a level of saturation and it is expected that imports would not go beyond this figure. The landed cost of the imported bulk drugs works out to be Rs. 150 crores. The current level of production of bulk drugs is about Rs. 220 crores and the projects in the pipeline which are expected to be implemented soon would give a turn-over of about Rs. 45 crores. Thus the additional requirement of bulk drugs for which new capacities are required to be created works out to about Rs. 400 crores for which an investment of about Rs. 275 crores is estimated to be required.

With regard to formulations, the current investment yielded a turn-over of Rs. 1150 crores during 1979-80. With the requirement of bulk drugs at Rs. 815 crores by 1984-85 the production of formulations would be of the order of Rs. 2450 crores. The additional quantum of formulations which has, therefore, to be produced works out to about Rs. 1300 crores. The investment to turn-over ratio in respect of formulations is about 1:4. Therefore, additional investment required for the production of this order of formulations works out to be Rs. 325 crores.

Thus the total additional investment required during the 6th Plan period in bulk drugs as well as in formulations would work out to about Rs. 600 crores. There is, however substantial spare capacity available in the formulation producing sector where capacity utilisation is at the moment, not more than 50%. With increasing demand, it is expected that capacity utilisation would increase which would, in real practice, not require setting up of many formulation plants. If, in the process, the capacity utilisation in the formulation industry is raised to about 80-85%, which would not be a difficult proposition and if this industry works for more than one shift in the production of formulations, in contrast to the present practice of one shift working, the investment required for the production of additional formulations worth Rs. 1300 crores would be appreciably smaller and would not exceed Rs. 50 crores. Thus the total investment required during the 6th Plan period would work out to be about Rs. 325 crores.

Since as per the New Drug Policy, the public sector units have to play a leading role, it is expected that substantial investment will come up through this sector. It is also expected that the Indian private sector would invest substantially during the Plan period. The following table gives the quantum of investment that is expected in the various sectors during the Plan period:—

	(Rs. in Crores) Bulk Drugs	Formulations	Total
1. Public Sector	140	20	160
2. Indian Private Sector including Small Scale Sector	90	25	115
4. Foreign Sector	45	5	50
Total	275	50	325

The expected production of bulk drugs as well as formulations in the various sectors of the industry during 1984-85 is expected to be as under:

	(Rs. in Crores) Bulk Drugs	Formulations
1. Public Sector	215	330
2. Indian Organised Sector	265	910
3. FERA Companies	135	720
4. Small Scale Sector	50	490
5. Imported Bulk drugs (landed cost)	150	—
Total	815	2450

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ANNEXURE—1

Demand Projections for Bulk Drugs for the Period 1979-80 to 1984-85

Sl. No.	Name of the Drug	Measuring Unit	Estimated Requirement						Rate of Growth % (Compound)
			1979-80 (Base Year)	1980-81	1981-82	1982-83	1983-84	1984-85	
	Antibiotics								
1.	Penicillin	MMU	350	440	560	700	900	1,150	27
2.	(*a*) Ampicillin	MT	90	105	120	140	160	180	15
	(*b*) Amoxycillin	MT	20	25	30	36	43	50	20
	(*c*) Other semisynthetics (Cloxacillin, Dicloxacillin, Carbenicillin, Epicillin, Methicillin etc.)	Kg	2,000	2500	3,125	3,900	4,900	6,100	25
3.	Streptomycin	MT	300	330	363	400	440	485	10
4.	Chloramphenicol	MT	250	262	275	290	305	320	5
5.	Tetracycline	MT	270	310	360	410	470	540	15
6.	Oxytetracycline	MT	115	131	150	171	195	220	14
7.	Doxycycline	Kg	7,000	7,700	8,500	9,400	10,250	11,250	10
8.	Erythromycin	MT	50	57	66	76	87	100	15
9.	Rifampicin	Kg	5,400	7,300	9,800	13,300	18,000	24,000	35
10.	Neomycin	Kg	8,000	8,400	8,800	9,250	9,700	10,200	5
11.	Framycetin	Kg	2,500	2,625	2,756	2,895	3,040	3,200	5
12.	Gentamycin	Kg	400	480	575	690	830	1,000	20
13.	Griseofulvin	Kg	8,000	9,200	10,580	12,170	14,000	16,000	15
14.	Bacitracin	BU	18	20	22	24	26	30	10
15.	Cephalosporine	Kg	1,500	1,950	2,535	3,295	4,285	5,570	30
16.	Cycloserine	Kg	1,500	1,650	1,815	2,000	2,200	2,420	10
17.	Kanamycin	Kg	450	520	595	685	790	905	15
	Sulphonamides								
18.	Sulphadimidine	MT	450	495	545	600	660	725	10
19.	Sulphaphenazole	MT	105	115	127	140	154	170	10
20.	Sulphasomidine	MT	235	258	284	313	344	378	10
21.	Sulphamoxole	MT	90	105	120	135	155	180	15
22.	Sulphamethoxazole	MT	90	110	135	165	202	250	22.5

Sl. No.	Name of the Drug	Measuring Unit	Estimated Requirement 1979-80 (Base Year)	1980-81	1981-82	1982-83	1983-84	1984-85	Rate of Growth % (Compound)
23.	Sulphaguanidine	MT	200	200	200	200	200	200	—
24.	Sulphadiazine	MT	200	210	220	230	245	255	5
25.	Sulphacetamide	MT	40	45	50	55	60	65	10
26.	Sulphamethoxypyridazine	Kg	10,000	10.500	11,000	11,600	12,200	12,800	5
27.	Sulphadimethoxine	MT	15,000	15,750	16,500	17,300	18,200	19,000	5
28.	Phthalyl sulphathiazole	MT	50	58	67	77	87	100	15
	Vitamins								
29.	Vitamin A	MMU	100	115	130	155	175	200	15
30.	Vitamin B_1								
	(*a*) Oral	MT	50	58	67	77	87	100	15
	(*b*) Injectable	MT	50	58	67	77	87	100	15
31.	Vitamin B_2	MT	30	35	40	45	52	60	15
32.	Vitamin B_6	MT	40	46	53	61	70	80	15
33.	Vitamin B_{12}	Kg	250	290	335	385	440	500	15
34.	Folic Acid	Kg	5,000	5,750	6,620	7,600	8,750	10,000	15
35.	Panthenol/Pantothenates	MT	45	52	60	70	80	90	15
36.	Vitamin C	MT	840	965	1,110	1,125	1,470	1,700	15
37.	Vitamin D_3	Kg	250	290	335	385	440	500	15
38.	Vitamin K and its derivatives	Kg	3,000	3,450	3,970	4,563	5,247	6,000	15
39.	Nicotinamide	MT	200	230	264	304	350	400	15
40.	Rutin	Kg	6,000	6,720	7,525	8,430	9,440	10,570	12
	Anti-Dysentery								
41.	Halogenated oxyquinolines	MT	300	330	365	400	440	485	10
42.	(*a*) Metronidazole	MT	90	105	120	140	160	185	15
	(*b*) Tinidazole	Kg	5,000	6,250	7,810	9,765	12,210	15,260	25
43.	Diloxanide furoate	Kg	12,000	12,600	13,250	13,890	14,600	15,300	5
44.	Furazolidone	MT	60	66	72	80	88	97	10
45.	Loperamide	Kg	—	—	—	—	—	2,000	—
	Anti-Diabetic								
46.	Insulin	MU	1,500	1,725	1,985	2,280	2,625	3,000	15
47.	Chlorpropamide	MT	20	23	26	30	35	40	15
48.	Tolbutamide	MT	25	25	25	25	25	25	—
49.	Glybenclamide	Kg	500	575	660	760	875	1,000	15
	Anti-T. B.								
50.	INH	MT	200	240	290	360	415	500	20

Sl. No.	Name of the Drug	Measuring Unit	Estimated Requirement 1979-80 (Base Year)	1980-81	1981-82	1982-83	1983-84	1984-85	Rate of Growth % (Compound)
51.	PAS	MT	600	630	660	700	730	770	5
52.	Thiacetazone	MT	40	42	44	46	48	50	5
53.	Ethambutol	MT	60	78	101	132	170	225	30
54.	Pyrazinamide	Kg	8,000	8,400	8,820	9,260	9,725	10,200	5
	Anthelmintics								
55.	Piperazine salts as hexahydrate	MT	240	265	290	320	350	390	10
56.	Bephenium hydroxy nephthoate	Kg	21,000	23,000	25,400	27,950	30,740	33,800	10
57.	Tetramisole/Levamisole	Kg	8,000	9,200	10,600	12,150	14,000	16,000	15
58.	Thiabendazole/Mebendazole	Kg	20,000	23,000	26,500	30,500	35,000	40,000	15
	Anti-Filarial								
59.	Diethylcarbamazine citrate	MT	30	33	36	40	45	50	10
	Anti-Malarial								
60.	Quinine	Kg	8,000	8,800	9,680	10,650	11,710	12,900	10
61.	Chloroquine	MT	250	275	300	335	365	400	10
62.	Amodiaquine	MT	40	46	53	61	70	80	15
63.	Primaquine	Kg	500	525	550	580	610	640	5
64.	Mepacrine	Kg	325	340	355	375	395	420	5
	Analgesics etc.								
65.	Pethidine	Kg	600	690	795	915	1,050	1,200	15
66.	Aspirin	MT	1,500	1,725	1,985	2,280	2,625	3,000	15
67.	Phenacetin	MT	125	125	125	125	125	125	—
68.	Paracetamol	MT	1,200	1,380	1,585	1,825	2,100	2,400	15
69.	Analgin	MT	750	825	910	1,000	1,100	1,200	10
70.	Dextropropoxyphene	Kg	6,000	7,200	8,640	10,370	12,140	15,000	20
71.	Indomethacin	Kg	1,000	1,100	1,210	1,330	1,465	1,600	10
72.	Phenylbutazone	MT	75	83	91	100	110	120	10
73.	Oxyphenbutazone	MT	55	64	73	84	96	110	15
74.	Allopurinol	Kg	250	288	330	380	435	500	15
75.	Ibuprofen	MT	35	42	50	60	72	85	20
	Anaesthetics								
76.	Procaine hydrochloride	MT	80	88	97	106	117	130	10
77.	Xylocaine	Kg	7,000	7,700	8,470	9,320	10,250	11,280	10
78.	Ether	MT	400	460	529	608	700	800	15
79.	Ethyl chloride	MT	20	22	24	27	29	32	10

Sl. No.	Name of the Drug	Measuring Unit	Estimated Requirement						Rate of Growth% (Compound)
			1979-80 (Base Year)	1980-81	1981-82	1982-83	1983-84	1984-85	
	Tranquilizers etc.								
80.	Chlorpromazine	Kg	6,000	6,600	7,260	8,000	8,800	9,700	10
81.	Phenobarbitone	MT	30	33	36	40	45	50	10
82.	Thiopentone	Kg	1,000	1,150	1,325	1,520	1,750	2,000	15
83.	Imipramine	Kg	1,600	1,840	2,116	2,430	2,800	3,200	15
84.	Amitriptyline	Kg	700	770	850	935	1,025	1,125	10
85.	Trifluoperazine and Trifluopromazine	Kg	4,000	4,600	5,300	6,100	7,000	8,000	15
86.	Diazepam	Kg	6,000	7,200	8,640	10,370	12,400	14,880	20
87.	Chlordiazepoxide	Kg	2,000	2,200	2,420	2,660	2,900	3,200	10
88.	Carbamazepine	Kg	4,000	4,800	5,760	6,900	8,290	10,000	20
89.	Meprobamate	Kg	18,000	19,800	21,780	23,960	26,355	29,000	10
	Anti-Histaminics								
90.	Pheniramine maleate	Kg	11,000	12,650	14,550	16,730	19,240	22,000	15
91.	Chlorpheniramine maleate	Kg	15,000	17,250	19,835	22,810	26,235	30,000	15
92.	Diphenhydramine	Kg	10,000	11,500	13,225	15,210	17,490	20,000	15
93.	Promethazine	Kg	2,000	2,200	2,420	2,660	2,930	3,220	10
	Antileprotics								
94.	Dapsone	MT	28	32	37	45	50	56	15
95.	Clofazimine	Kg	300	360	430	520	625	750	20
	Cardiovascular								
96.	Methyl dopa	MT	20	23	26	30	35	40	15
97.	Xanthinol nicotinate	MT	14	16	19	21	24	28	15
98.	Glyceryl trinitrate/ Isosorbide dinitrate/ Pentaerythrital tetranitrate	Kg	4,000	5,200	6,760	8,800	11,400	14,800	30
99.	Prenylamine lactate	Kg	950	1,090	1,255	1,445	1,660	1,900	15
100.	Digoxin	Kg	18	22	26	31	37	45	20
101.	Clofibrate	Kg	3,000	3,300	3,650	4,000	4,400	4,850	10
102.	Clonidine	gm	1,000	1,150	1,320	1,520	1,750	2,000	15
103.	Propranolol	Kg	4,900	6,150	7,680	9,600	12,000	15,000	25
104.	Dipyridamol	Kg	800	920	1,060	1,220	1,400	1,600	15
	Diuretics								
105.	Frusemide	Kg	5,000	6,000	7,200	8,640	10,400	12,500	20
106.	Hydrochlorothiazide	Kg	4,000	4,800	5,760	6,910	8,300	10,000	20

Sl. No.	Name of the Drug	Measuring Unit	Estimated Requirement						Rate of Growth % (Compound)
			1979-80 (Base Year)	1980-81	1981-82	1982-83	1983-84	1984-85	
	Anti-Asthmatics								
107.	Ephedrine	MT	50	55	60	66	73	80	10
108.	Aminophylline/Theophylline/ Hydroxyethyltheophylline/ Other derivatives	MT	110	125	145	167	192	220	15
109.	Salbutamol	Kg	550	660	790	950	1,140	1,370	20
110.	Phenylepherine	Kg	2,150	2,365	2,600	2,860	3,150	3,460	10
111.	Terbutaline	MT	—	—	—	—	—	2	—
	Steroids and Hormones								
112.	Dexamethasone	Kg	300	345	400	460	520	600	15
113.	Betamethasone	Kg	350	400	460	530	610	700	15
114.	Prednisolone	Kg	2,100	2,410	2,770	3,190	3,675	4,225	15
115.	Triamcinolone	Kg	70	77	85	93	102	112	10
116.	Norethisterone	Kg	170	195	225	258	297	340	15
117.	Norgestrol	Kg	50	57	66	76	87	100	15
118.	Nandrolone & its esters	Kg	100	110	120	135	146	160	10
119.	Oxytocin	MU	1,400	1,540	1,695	1,860	2,050	2,255	10
120.	Testosterone esters	Kg	450	495	545	600	660	725	10
	Anti-Epileptics								
121.	Diphenyl hydantoin	MT	15	17	20	23	27	30	15
	Anti-bacterials other than Antibiotics and Sulphonamides								
122.	Nitrofurantoin & Nitrofurazone	MT	20	22	24	27	29	32	10
123.	Trimethoprim	MT	25	31	39	49	61	76	25
	CNS Stimulants								
124.	Caffeine	MT	132	152	175	200	230	265	15
	Anti-Cancer								
125.	Cyclophosphamide	Kg	220	286	372	484	629	820	30
126.	5-Fluorouracil	Kg	100	130	169	220	286	372	30

PROCESSES DEVELOPED BY CENTRAL DRUG RESEARCH INSTITUTE, LUCKNOW AVAILABLE FOR COMMERCIALISATION

A total of 53 processes covering synthetic drugs as well as biologicals and plant products have been developed by Central Drug Research Institute, Lucknow. Some processes are being commercially exploited by a number of industries. Non-technical notes about the processes are available to interested entrepreneurs from NICDAP or Technical Information and Industrial Liaison Division, CDRI. Following is the list of processes:—

Sl. No.	Product	Starting Material	Use
Synthetics			
1.	Adrenaline	Catechol	Bronchial antispasmodic
2.	Adrenochrome monosemicarbazone	Adrenaline	Control of capillary bleeding
3.	Amphetamine	Phenylacetone	C.N.S. stimulant and anorexic agent
4.	Centimizone	Ethylenediamine	Antithyroid for treatment of thyrotoxicosis
5.	Chenodesoxycholic acid	Cholic acid	For dissolution of gall stone
6.	Chlorpheniramine maleate	*p*-Chlorobenzylchloride	Antihistaminic
7.	Choline chloride	Ethylene chlorohydrin	Lipotropic agent
8.	Clonidine	2,6 Dichloroaniline	Antihypertensive
9.	Cyclophosphamide	Diethanolamine	Antineoplastic
10.	D.D.S. (Diaminodiphenyl sulphone)	(*i*) Chlorobenzene (*ii*) *p*-Chloronitrobenzene	Antileprotic
11.	Daraprim	2-Aminopyrimidine	Antimalarial
12.	Dehydroepiandrosterone	Diosgenin	Drug intermediate
13.	5,7-Dichloro-8-hydroxyquinoline	8-Hydroxyquinoline	Antibacterial, antifungal antiamoebic
14.	Diloxanide	*p*-Aminophenol	Antiamoebic

Sl. No.	Product	Starting Material	Use
15.	5,6, Dimethyl benzimidazole	o-Xylidine	Drug intermediate
16.	Diphenylhydantoin sodium	Benzaldehyde	Antiepileptic
17.	Ethambutol	2-Aminobutanol	Tuberculostatic
18.	Furazolidone	5-Nitrofuraldehyde diacetate	Antibacterial, antifungal, antiprotozoal
19.	8-Hydroxyquinoline	Quinoline	Antibacterial, drug intermediate
20.	Indomethacin	p-Anisidine	Anti-inflammatory
21.	Isoprenaline (dl)	Catechol	Bronchodilator
22.	Lamprene	3-Nitrochlorobenzene p-Chloroaniline	Antileprotic
23.	Levulinic acid & calcium levulinate	Sucrose	Drug intermediate and used in calcium deficiency
24.	Lidocaine	2,6—Xylidine	Local anaesthetic
25.	Methamphetamine	Phenylacetone	CNS stimulant and anorexic agent
26.	Metol	p-Aminophenol	Drug intermediate, photographic chemical
27.	Metronidazole	Glyoxal, acetaldehyde	Antiprotozoal, antiamoebic
28.	Nicotinic acid and Niacinamide	β-Picoline	Vitamins
29.	Nitrofurantoin	5-Nitrofuraldehyde diacetate	Antibacterial used in uinary tract infection
30.	Nitrofurazone	5-Nitrofuraldehyde diacetate	Antibacterial used in topical application
31.	Paracetamol	Phenol	Antipyretic, analgesic
32.	Primaquin	p-Anisidine	Antimalarial
33.	Procaine	Benzocaine	Local anaesthetic
34.	d-Propoxyphene	Propiophenone	Analgesic
35.	Racephedrine	Propiophenone	Sympathomimetic, bronchodilator
36.	Sodium valproate	Malonic ester	Anticonvulsant, antiepileptic

Sl. No.	Product	Starting material	Use
37.	Sulphamethoxazole	Hydroxyurea	Antibacterial
38.	Thiacetazone	p-Nitrotoluene	Tuberculostatic agent
39.	Thiosemicarbazide	Hydrazine sulphate	Drug intermediate
40.	Tolazoline hydrochloride	Benzyl cyanide	Treatment of peripheral vascular disorders
41.	Trimethoprim	Gallic acid, acrylonitrile	Antibacterial
Biologicals and Plant Products			
42.	Casamino acid	Casein	Bacteriological media constituents
43.	Hesperidin	Orange peel	Skin nutrient
44.	Protein hydrolysate	Groundnut cake	Nutritive supplement
45.	Psoralen	Babchi (*Psoralea*) seeds	Pigmentogenic agent
46.	Tocopherol	Rice bran	Nutritive supplement
47.	Tryptone	Casein	Media constituent
48.	Cholic acid and dehydrocholic acid	Buffalo bile	Hydrochloretic
49.	Pepsin	Stomach mucosal lining	Digestive enzyme
50.	L-Dopa	Mucuna prurita seeds	Anti-parkinsonism
51.	Peptone & meat extract	Buffalo meat	Media constituent
52.	Proteose peptone	Buffalo meat	Media constituent
53.	Plasma fractions		
	(*i*) Plasma albumin	Human/bovine blood	Treatment of shock
	(*ii*) Human immunoglobulin	Blood	In prophylaxis of measles, jaundice, rubella and for treatment of gammaglobulinemia
	(*iii*) Human immunoglobulin	Placenta	

DRUGS AND PHARMACEUTICALS MANUFACTURERS IN U. P.

Uttar Pradesh, the most populated state of our country has a total of 361 manufacturers of drugs and pharmaceuticals licenced under Drugs and Cosmetics Act 1940. Out of the 54 districts of the state only 38 have drug units while rest have no drug industry. Kanpur and Meerut districts each have about 50 units, manufacturing almost all forms of drugs i.e., tablets, capsules and injectables, etc. The detailed list of manufacturers is as under:—

AGRA (DISTT.)

M/s Agra City Blood Bank,
Mahatama Gandhi Road, Agra.

M/s Agra Pharmaceutical Laboratories
613 G-Shastrinagar, Agra.

M/s Biological Evans,
Bodla, Near S. R. Industries,
Bichpuri Road, Agra.

M/s B. P. Oil Mills Ltd.,
Mithan, Agra.

M/s Curesx Pharma,
10, Shanti Nagar (Police Line)
Fatehpur Shikari Road, Agra.

M/s Marigold Laboratory,
82/158 Moti Lal Nehru Marg,
Agra.

M/s Master Balm Pharmacy,
Deohri Begum, Agra-3.

M/s. Mittal Chemical Industries,
4/54 Hathras Road, Naraich
Near Ram Bagh, Agra.

M/s Para Chem Pharma,
Maheshwari Building,
Durga Nagar, Agra.

M/s Pee Medica,
Shastri Nagar, Near Police Station
Fatehpur Sikri Road, Agra.

M/s Petro Tec, Fatehpur Sikri Road,
Opposite-Pritha-vinath Mandir, Agra.

M/s Rashtra Deep Laboratories,
Ferojabad, Agra.

M/s Satsheel Products,
28/336, Gokulpura,
Bihari Ji Ki Gali, Agra.

M/s Standard Blood Bank & Pathology
Laboratory, 15/491, Kali
Bari Road, Agra.

M/s Vasco Drug Laboratory,
42/327, Bilochpura, Agra.

M/s Vishwa Laboratories,
Bah-Distt. Agra.

M/s V. S Dutta Manufacturer,
9/149 Motibag, Janwara Bridge, Agra.

ALIGARH (DISTT.)

M/s. Bal Jiwan Karyalaya,
Masoodabad, Aligarh.

M/s Bharat Pharma & Chemicals,
A-5-6 Industrial Estate, Hathras Road,
Aligarh.

M/s Dr. Ganga Prasad Gupta, & Sons,
Motibazar, Hathras, Distt. Aligarh.

M/s Karan Prakash Laboratories,
Agra Road, Hathras, Distt.
Aligarh.

M/s New India Surgical Corpn.,
Atrauli, Distt. Aligarh.

M/s Pankaj Pharma,
D-79, Industrial Estate,
Aligarh.

M/s Prakash Surgical Industries,
Begumbag, Aligarh.

M/s Supper Standard Chemical Mfg. Co,
Drugs Mansion, Agra Road,
Aligarh.

M/s Union Pharma,
7-Industrial Estate,
Aligarh.

M/s Vijai Chemical Industries,
Naranjan Puri, Ramghat Road,
Aligarh.

ALLAHABAD (DISTT.)

M/s Amit & Co,
Allahabad

M/s Baidyanath Ayurved Bhawan (P) Ltd.,
Naini, Allahabad.

M/s Bibgyor Laboratories India,
34/41, Industrial Colony, Naini,
Allahabad.

M/s Chemido Enterprises (P) Ltd.,
170/1, Noorullah Road,
Allahabad.

M/s Dey's Medical Stores,
Manufacturing (U. P.) Ltd.,
Naini, Allahabad.

M/s Gandhar Enterprises,
27-B Monerco Industrial Estate,
Teliarganj, Allahabad.

M/s Indian Remedies,
Vimala Sadan, 71,
Nehru Nagar, Allahabad.

M/s J. K. Central Blood Bank,
8-A, Bank Road, Allahabad.

M/s Kohinoor Chemical Industries,
Allahabad.

M/s Oculus Pharmaceuticals,
87/A-1 Nortion Kalaka, Allahabad.

M/s Optho Remedies,
522-A Rajapur, Allahabad.

M/s Pioneer Pharmaceutical (P) Ltd ,
522-A, Rajapur Facing, Stanley Road,
Allahabad.

M/s Prakash Insecticide (P) Ltd.,
Naini Allahabad.
Allahabad.

M/s Premier Laboratories (P) Ltd.,
45-Subedar Ganj Allahabad

M/s Ramsay Pharma (P) Ltd.,
Industrial Area,
Naini, Allahabad.

M/s Ramsy pharma (P) Ltd.
Mirzapur Road, Allahabad.

M/s Sosicend Pharmaceuticals (P) Ltd,
Industrial Area,
Naini, Allahabad.

ALMORA (DISTT.)

M/s Co-operative Drug Factory,
Udaynagar, Ranikot, Almora.

M/s Alps Labs,
Almora.

AZAMGARH (DISTT.)

M/s Devit Pharma. Mohamdabad,
Gohana, Azamgarh.

M/s Medical Pharma,
Mohamdabad, Gohna, Azamgarh.

BARABANKI (DISTT.)

M/s New International Chemical (P) Ltd,
Civil Lines, Barabanki.

BAREILLY (DISTT.)

M/s Ayurvedic Research Laboratory,
Near City Station, Bareilly.

M/s Bharat Pharmaceuticals Works,
Old Match Factory, Bareilly.

M/s Camphor & Allied Product Ltd.,
Collectorbuckganj, Bareilly.

M/s Kios Beauty International
35, A Rampur Garden, Civil Lines, Bareilly.

M/s Nova Pharma, 118, Kaharwan,
Beharipur, Bareilly.

M/s Sarpal Pharmaceuticals (P) Ltd.,
Industrial Estate, Bhojipura, Bareilly

M/s S. Ravico (P) Ltd.,
304, Kalibari, Bareilly.

M/s Terpentine Subsidiary Industries,
Collectorbuckganj, Bareiliy.

M/s Triveni Surgical Industries,
348, New Montessary School, Kahar
Vari, Beharipur, Barelly.

BASTI (DISTT.)

M/s Enkeys Chemicals,
Bhatia Bhawan, Opp. Railway Station,
Basti.

BIJNOR (DISTT.)

M/s Cosmos Surgical & Dressing Product
Nigtaur,
Bijnor.

M/s Rajeev & Sanjay Seohar,
Bijnor.

BULANDSHAHAR (DISTT.)

M/s Deo Surgical & Dressing Manufacturing
Co., 46 Nayaganj, Khurja, Distt.
Bulandshahr.

M/s Leana Product.
508 A-City Station Road,
Khurja, Distt. Bulandshahr.

M/s National Surgical, 80-M, Malui Marg,
Khurja, Distt. Bulandshahr.

DEHRADUN (DISTT.)

M/s Amrit Dhara Pharmacy (P) Ltd.
97, Rajpur Road, Dehradun.

M/s Baldhara Pharmacy, 24 EC Road,
Dehradun.

M/s Bengal Immunity,
59, Rajpur Road, Dehradun.

M/s Indian Drugs & Pharmaceuticals Ltd.,
Rishikesh, Distt. Dehradun.

M/s New India Chemical & Pharmaceuticals
Works,
Chendni Road, Dehradun.

Pratap Pharma,
Rajpur Road, Dehradun.

M/s Ramko Chemical Laboratory,
125, Kaulagarh Road, Dehradun.

M/s Rewa Dhamdha,
176, Ajabpur Kalan,
Dehranpur, Dehradun.

M/s Rinco Pharmaceuticals,
210-B. D. L. Road, Dehradun.

M/s Satnam Pharmaceuticals,
74/3 Chakrata Road, Dehradun.

M/s Sushil Jet & Co.
114, Saharanpur Road, Dehradun.

M/s Tibetan Nehru Medical Foundation,
Amod Colony,
Clement Town, Dehradun.

ETAH (DISTT.)

M/s Shakti Pharma, Kash Ganj,
Distt. Etah.

ETAWAH (DISTT.)

M/s Anandkar Karyalaya (P) Ltd,
Etawah.

M/s Ratnakar Laboratory,
Aurauya Road, Etawah.

M/s Subhala Pharmacy,
Aurauya, Etawah.

FAIZABAD (DISTT.)

M/s Anant Aushdhalaya,
Mohalla Bazar, Paizabad.

M/s Kaya Kalp Hair Oil,
Bhawan, Januara, Fazabad.

FARRUKHABAD (DISTT.)

M/s Mukti Pharma,
Post Office Road, Kaiyamganj,
Farrukhabad.

M/s Primus Chemicals Works,
Thakurana Road, Kannauj, Farrukhabad.

FATEHPUR (DISTT.)

M/s U. P. Absest. (P) Ltd.,
Pindki Mughal Road, Fatehpur.

GHAJIPUR (DISTT.)

M/s Anand Rural Industries,
Nang ganj, Ghajipur.

M/s Dabur (Dr. S. K. BURMAN) (P) Ltd,
Sahabad, Ghazipur.

M/s Manager, Govt, Opium & Alkaloid
Works,
Ghajipur.

GHAZIABAD

M/s Anvee Pharmaceuticals, D-4/5, Sahibabad,
Ghaziabad.

M/s Biomed (P) Ltd.,
C-96, Site No. 1, Industrial Area,
Bulandshahar Road, Ghaziabad.

M/s B. N. & Co. D-36 Industrieal Area
Bulandshahar Road, Ghaziabad.

M/s Dee Cu Laboratories,
44, Rajendra Nagar, Industrial Estate,
Ghaziabad.

M/s Bombay Chemical, Kumar Bhawan,
G. T. Road, Opp. Civil Hospitol,
Ghaziabad.

M/s Ellylilly (India), 123. Guldhar,
Ghaziabad.

M/s Emson & Co., B-16, Site No. 3,
Iudustrial Estate, Ghaziabad.

M/s Federal Chemical Works,
C-2, Industrial Area,
Sector 22, Ghaziabad.

M/s Gal-Seal Pharmac Industrial Estate,
Mohan Nagar, Ghaziabad.

M/s G. D. Pharmaceutcials,
Rajendranagar, Ghaziabad.

M/s Hamdard Waqf Lab.,
Site No. 3, Industrial Area,
Ghaziabad.

M/s Hindustan Oxygen Acetyline,
G. T. Road, Ghaziabad.

M/s Kamal Industries & Allied Product
(P) Ltd., 26/1 Site No. 4 Sahibbad,
Ghaziabad.

M/s Kasmo Pharmaceuticals, (P),
Goal-dhar, Ghaziabad.

M/s Medicines Pharmaceuticals,
193, Brindaban Gardan,
Ghaziabad.

M/s Medicose Pharma, Central Works,
143, Brindaban Garden, Ghaziabad.

M/s Medicura Drug & Pharmaceutical Lab.
C-13, Industrial Area, Meerut Road,
Ghaziabad.

M/s M. M. Lab., D-10, Industrial Estate,
Ghaziabad.

M/s M. M. Lab. Meerut Road,
Ghaziabad.

M/s Mohan Meakins Breweries,
Mohan Nagar, Ghaziabad.

M/s National Chemical & Pharmaceutical
Works, Meerut Road, Ghaziabad.

M/s Omega Pharmaceuticals,
C-7, Industrial Estate,
Meerut Road, Ghaziabad.

M/s Pharmaceuticals (170) Milora,
India, S-4 Loni Industries Area,
Loni, Ghaziabad.

M/s Pyya Pharmaceutical works,
Mohan Nagar, Ghaziabad.

M/s S.B.V. Cosmetic (India) G-2,
Shashtri Nagar, Ghaziabad.

M/s Super Pharma,
69, Anand Industrial Estate, Ghaziabad.

M/s Swarup Pharmaceutical, 49,
Arjun Nagar, Ghaziabad.

M/s Swastic Pharmaceuticals,
56, Dayanand Nagar, Ghaziabad.

M/s Tata Oil Mills Co. Ltd.,
Loni Road, Ghaziabad.

M/s Techna Pharma India,
R-4/118, New Rajnagar, Ghaziabad.

M/s Unichem Lab.,
10, Anand, Industrial Estate,
New Mohan Nagar,
G. T. Road, Ghaziabad.

M/s Unichem Laboratories Ltd.,
C-32 Industrial Area, Meerut Road,
Ghaziabad.

M/s Uni.-U.C.B. (India) (P) Ltd.,
Ghaziabad.

M/s Ward Blenkinsop & Co. (India) Ltd.,
C-15, Industrial Area Site No. 4, Sahibabad,
Ghaziabad.

M/s Weston Pharmaceuticals,
82, Anand Industrial Estate,
Mohan Nagar, Ghaziabad.

GORAKHPUR (DISTT.)

M/s Lamal Pharma Industrial Estate,
Gorakhpur.

M/s New Blood Bank, Alinagar,
Gorakhapur.

HAMIRPUR (DISTT.)

M/s Maidka Chemicals, Gandhi Nagar,
Hohalla, Distt., Hamirpur.

HARDOI (DISTT.)

M/s Asian Traders Malkhana,
Sandila, Hardoi.

M/s Handloom Dressing Corpn.,
Sandila, Hardoi.

M/s Bharat Handloom Industry,
Mangal Bazar, Sandila, Hardoi.

M/s Calcutta Handloom Industry,
Ashraf Tola, Sandila, Hardoi.

M/s M. A. Weaving & Sales Corpn.
Society Sandila, Hardoi.

M/s Sandila Handloom Industries,
Sandila, Hardoi.

JAUNPUR (DISTT.)

M/s Prakash Surgical Industries,
Shri Niwas, Phapur Road,
Jaunpur.

JHANSI (DISTT.)

M/s Bundelkhand Ayurvedic Unani
Pharmaceuticals Works,
Jhansi.

M/s M. L. B. Medical College,
Jhansi.

M/s Shree Baidhya Nath Ayurvedic Bhawan
Ltd,, Gharior Road, Jhansi.

KANPUR (DISTT.)

M/s Abgel Pharma (P). Ltd,
U-6 Niralanagar, Kanpur.

M/s Alankar Pharmacy,
Halsi Road, Kanpur.

M/s. Anand Sagar Karyala,
Daulat Ganj, Kanpur.

M/s Apexco Pharma,
118/257 Kaushal puri, Kanpur.

M/s Bengal Chemical & Pharmaceuticals
Works, Kanpur.

M/s Bhawani Pharmaceuticals (P). Ltd.,
D/4-G-Panki Industrial Estate, Kanpur.

M/s Doctor Pharmaceuticals,
P-11 Rattu Purwa, Kanpur.

M/s Drug Corporation,
Bithur Road, Kanpur.

M/s Eastern Agencies,
132/429, Azad Nagar, Bahupura, Kanpur.

M/s Electrosal Pharma,
8/128, Aryanagar, Kanpur.

M/s Friends Pharmaceuticals,
12/509, New Gwaltoli, Kanpur.

M/s Flora Pharma (P). Ltd.,
289, Dadnagar, Kanpur.

M/s General Pharmacuticals,
P-22, Pratap Ganj, Kanpur.

M/s Gillina Pharmaceuticals,
117/H-2/168Pandu Nagar, Kanpur.

M/s Harrison Laboratories, Mercantile
Building,
40/101 Hospital, Kanpur.

M/s Hind Chemical Ltd.,
H. G. 863 Sirkar Road, Kanpur.

M/s Ideal Chemicals Works (P) Ltd,
110/79, Ram Krishna Nagar, Kanpur.

M/s Industrial Gases Ltd,
40-Factory Area, Fazal Ganj, Kanpur.

M/s Jai Chemicals Industries,
123/378 Fajal Ganj,
Kanpur.

M/s K. B. Industries,
89/208, Bans Mandi, Kanpur.

M/s Kaiya Corporation,
647, M-1 Juhi Soth,
Kanpur.

M/s Kanpur Kambal & Yarn Spinners,
1-Industrial Estate,
Kanpur.

M/s Kaynath Pharmaceuticals,
123/378, Fazal Ganj, Kanpur.

M/s Kumaun Pharmaceuticals,
15/198, Civil Lines, Kanpur.

M/s Kunwar Ayurvedic Pharmacy,
16/14, Rayon Road,
Civil Lines, Kanpur.

M/s Madimix 17/3 Behari Lal,
Estate, The Mall, Kanpur.

M/s Marine Woollen Mills,
394/865, Jajamau, Road, Kanpur.

M/s National Enterprises,
Flat no. 6-1, Panki Industrial Estate,
Kanpur.

M/s Parkar Pharma (P) Ltd.
84/10, Fazal Ganj, Kanpur

M/s Pharma Lab. (P) Ltd.,
128/364, K-Block, Kidwai Nagar, Kanpur.

M/s Pharmaceuticals & Allied Mfg. (P) Ltd,
64, Udya Nagar, Kanpur.

M/s Pilco Pharma,
117/622, Paravti Kuti, Pandu Nagar,
Kanpur.

M/s Prakash Chemical Works,
392 Harjinder Nagar, Kanpur.

M/s Proto Pharma (P). Ltd.
'K' 369, Kidwai Nagar, Kanpur.

M/s Ethical Pharmaceuticals,
58/33, Birhana Road, Kanpur.

M/s Rag & Co.,
111/151, Harish Nagar, Kanpur.

M/s Shree Gopal Engg. Works
91, Govt. Industrial Estate, Kanpur.

M/s Shyam Chemical (India),
13/3-H The Mall, Kanpur.

M/s Singar Pharma, 117/H-
2/54 Pandu Nagar, Kanpur.

M/s Spun Pharma,
U-7 Nirala Nagar, Kanpur.

M/s S. Ravi Trading Corporation,
109/400 Nehru Nagar, Kanpur.

M/s Star Agencies, 20/47,
Birhana Road, Kanpur.

M/s Star Chemicals,
84/170, Thakur Wati, G. T. Road, Kanpur.

M/s Surgico Product,
89/148, Bansmandi, Kanpur.

M/s Techno Pharma (P) Ltd,
3/100 Vishnupuri, Kanpur.

M/s U. P. Co-operative Knitting & Weaving
Society, 15/4, Civil Lines, Kanpur.

M/s. U. P. Pharmaceuticals,
113/188 Sawarupnagar, Kanpur.

M/s Universal-Pathology-Laboratory &
Blood bank, Opp. L.L.R. Hospital, Kanpur.

M/s Venus Industries,
194-B Co-operative Industrial Estate,
Kanpur.

M/s Vigyan Pharma,
56/44 Birhana Road, Kanpur.

M/s Vikrant Chemicals Industries,
49-Industrial Estate, Kanpur.

LALITPUR (DISTT.)

M/s Sidhi Pharma (P) Ltd.,
Lalitpur.

Anupum,
Civil Lines, Lalitpur.

LUCKNOW (DISTT.)

M/s Appika (P) Ltd.,
Laxmi Bhawan, Aishbagh, Lucknow.

M/s Arora Laboratories,
Outram Road, Lucknow.

M/s Bharat Chemical & Pharmaceutical
Laboratory, 191, Faizabad Road,
Lucknow.

M/s Biochem Drug Lab.,
Goods Shed Road, Aishbagh, Lucknow.

M/s Crimson Laboratory, B-25,
Mahanagar, Lucknow.

M/s Deepak Cosmetic 893/32,
Ganeshganj, Lucknow.

M/s Disinfecto Chemical Industry
Bara Birwa. Kanpur Road, Lucknow.

M/s Ellora Traders, 678 Kailash
Bhawan, Rajendra Nagar, Lucknow.

M/s Garga Pharma Pvt. Ltd.,
Talkatora Road, Lucknow.

M/s General Pharmaceuticals
Chemicals Works, 29, Jopling Road,
Lucknow.

M/s G-Praxen & Co., (P) Ltd.,
Tulsi Das Marg, Lucknow.

M/s Grosen Pharmaceuticals,
Near Amousi Airport,
Kanpur Road, Lucknow.

M/s Hindustan Handloom Industry,
62-Kaccha Hata, Aminabad, Lucknow.

M/s Hindustan Laboratories,
9-D, Sarojininagar, Lucknow.

M/s Indian Chemical (P) Ltd.,
24-Crowmten Road, Chowk, Lucknow.

M/s Indian Petroleum & Chemical
Industries, 195/97, Crown gate
Jagat Narain Road, Lucknow.

M/s. Indian Pharma,
9, B. N. Road, Lucknow.

M/s Indian Surgicals,
Mauribag-Telibag, Lucknow.

M/s Industrial Gases, 148-
Talkatora Road, Lucknow.

M/s International Pharmaceuticals
Corporation, Ranapratap Marg, Lucknow.

M/s Krishna Chemicals,
43-C Cantonment Road, Lucknow.

M/s Labros Chemicals,
Sitapur Road, Lucknow.

M/s Lucknow Scientific & Surgical
Corporation, 8 Kaisherbagh, Lucknow.

M/s Medi Product, Dafti Mill
Compound, Yogeshwar Nath Road,
Old Tikaitganj, Lucknow.

M/s Medicin India,
B-17, Sindhu Nagar, Lucknow.

M/s Modern Pathology,
8, Kamala Nehru Marg, Lucknow.

M/s Mogrita Pharma, Sanatan Dharma
Mandir Building, Singarnagar,
Lucknow.

M/s Pharmachem Laboratory,
4, Ajanta Copper Road, Lucknow.

M/s Primex Petroleum & Pharmaceuticals
(P) Ltd., Iqbal Palace,
Wazir ganj, Lucknow.

M/s Rohit Pharma, Bharat Niwas,
Tilak Nagar, Lucknow.

M/s Ruby Chem Laboratory,
13-A, Krishna Nagar, Lucknow.

M/s Rup Chemical (P) Ltd.,
Mansoor Nagar, Lucknow.

M/s Scientific Research Industries,
Chhitwapur Road, Lucknow.

M/s Sigma Chemical & Pharmaceutical
Labs, 46-A, Krishan Nagar, Lucknow.

M/s. S. H. I. Medical College
Campus, Lucknow.

M/s Sunlight Chemical Works,
58-C, Singar Nagar, Lucknow.

M/s Surya Chemical,
Daliganj, Lucknow.

M/s Syntho-Pharmaceutical (P) Ltd.,
E-6, Industrial Estate,
Talkatora Road, Lucknow.

M/s U. P. Drug House (P) Ltd.
29, Major Bank Road, Lucknow.

M/s United Research Intstitute,
98, Chandra Nagar, Lucknow.

M/s United Remedies India (P) Ltd.,
A-6, Krishna Nagar, Lucknow.

Uttar Pradesh Drugs & Pharmaceuticals Co.
Ltd., A-5, Industrial Area,
Kanpur Road, Lucknow

M/s Vivek Industries,
Yogeshwar Nath Marg,
Tikait Rai Talab, Lucknow.

M/s V. Pharma Labs. (P) Ltd.,
26, Chandra Lok, Lucknow.

MAINPURI (DISTT.)

M/s Kappsons Pharamaceuticals,
Mainpuri.

MATHURA (DISTT.)

M/s Asli Dawakhana,
1872, Tilak Bhawan, Mathura.

M/s Laxmi Chemical Industries,
Krishna Nagar, Sonkh Road,
Mathura.

M/s Palkse Pharma,
808 Chotta Bazar, Mathura.

M/s Sukh Sancharak Co., Mathura.

MEERUT (DISTT.)

M/s A. B. M. Research Institute for
Biological, Shrinagar,
Railway Road, Hapur.

M/s A. B. M. Research Institute,
Non-Biological, Rajendra Nagar,
Railway Road, Hapur.

M/s Abnex Laboratories,
Ahmad Road.
Khairnagar, Meerut.

M/s Allodial Chemical Manufacturing Co.
(P) Ltd.,
711. Khairnagar Street, Meerut.

M/s Apex Traders,
272/2 Prempuri, Meerut.

M/s Apolo Surgical,
11-C Sotiganj Gurdwara Road, Meerut City.

M/s Athichem (P) Ltd.,
Moradnagar, Meerut.

M/s Bardlly Laboratory,
62, Saket, Meerut.

M/s Bengal Phenyl & Allied Products,
44-45 Garh Road, Meerut.

M/s Bharat Sales Corporation,
770/1, Sotiganj, Meerut.

M/s Brita Agencies,
127-A, Rangsaz, Meerut.

M/s Candour Pharmaceutical,
Bulaki Dass Building,
Begum Bridge, Meerut.

M/s Chem India Pharmaceuticals,
Gali No. 4, Panchsheel Colony,
Garh Road, Meerut.

M/s Dashmesh Surgical Industries,
A/10 Jawahar Quarter Police Station,
Lalkurti, Meerut.

M/s Eastern Drugs,
Sanitary Products,
229 Sutigang, Meerut.

M/s Everest Lab.,
Meerut.

M/s Fanny Pharmaceuticals,
E-4, Sarai Nagar Ali,
G. T. Road, Meerut.

M/s Guru Nanak Surgical Corporation,
Dasmesh Nagar, Meerut.

M/s Handson Tudor Cosmetic,
33, Jain Nagar, Meerut City.

M/s Himalaya Surgical,
134, Jatti-Bara, Meerut.

M/s Himalayan Surgical,
67/68, Santinagar,
Railway Road, Meerut.

M/s Indochem Lab.
75, Boundary Road, Meerut.

M/s Indo Chem Pharmaceuticals (P) Ltd.,
75-Bombay Road, Meerut.

M/s J. P. Sharma & Co.
Sarai Khair Nagar,
Opposite Filmistan Cinema, Meerut.

M/s Kamala Nehru Blood Bank,
Prakash Villa, Mission Compound,
Begum-bridge Road, Meerut.

M/s. L Mithan Lal,
3 Co-105-106 Chippiwar Street, Meerut.

M/s Martand Pharmaceuticals,
Baraut, Distt. Meerut.

M/s Medicine Traders Manufacturing Division, 11-A Bhawani Nagar,
Hapur Road, Meerut.

M/s Medico Pharma (India),
1162, Baghpat Gate, Meerut.

M/s Medicura Lab. (P) Ltd.,
4 Panchsheel Colony,
Garh Road, Meerut.

M/s Modi Gas Chemical,
Modinagar, Meerut.

M/s Mohan & Co.,
1388 PL Sharma Road,
Begum bag, Meerut.

M/s Ambica Surgical Traders,
Sotiganj, Meerut.

M/s Nelsons & Co.,
309 RA Bazar, Meerut.

M/s Nion Laboratories,
Shivaji Road, Meerut.

M/s Nixon Surgical Works,
Subash Nagar, Meerut.

M/s Northern India Chemical Works (P) Ltd.
Near Sardhana Railway Crossing, Meerut.

M/s Paul Surgical,
237, Topchiwala Street,
Meerut City.

M/s Pearson Chemical Corporation,
Muktiwara, Meerut City.

M/s Ray light & Co., 388, Western
Kachehri Road, Meerut.

M/s Senith Corporation,
5-A, Jain Nagar, Meerut.

M/s Shakti Chemical Works,
Meerut.

M/s Specia Pharmaceuticals,
711, Khairnagar Street, Meerut.

M/s Subhash Traders,
167/1, Anandpuri,
Railway Road, Meerut.

M/s Suraj Surgical Industries,
B-19, Industrial Estate,
Pratappur, Meerut.

M/s Swastic Surgical Manufacturing Corporation,
106/1, Saket Road, Meerut

M/s U. P. Surgical,
D-17/88, Industrial Estate,
Pratappur, Meerut

M/s U. P. Surgical Industries,
I-17/18 Industrial Estate,
Pratappur, Meerut.

M/s V. G. P. Laboratory,
Meerut.

M/s Winton Industries,
B-53 Jain Nagar, Meerut.

MIRZAPUR (DISTT.)

M/s Varanasi Phenyl Mfg. Co., Obra,
Mirzapur.

MORADABAD (DISTT.)

M/s Acme Surgical & Dressing,
Mohalla Ghosipura, Moradabad.

M/s A. R. Product (India),
P. O.: Sarai Tarin, Moradabad.

M/s Avon Weaving Factory,
Kanth, Moradabad

M/s Bishnoi Surgical Factory,
Kanth, Moradabad.

M/s Bynol Pharma,
Rain Basera, Harthala, Moradabad.

M/s Chandausi Chemical Works,
Sita Road, Chandausi, Moradabad.

M/s C. K. Chemical Works,
Joya Road, Amroha, Distt. Moradabad.

M/s Deekay Pharma (India) (P) Ltd..
Prince Road, Moradabad.

M/s D. R. Surgical A-56,
Gandhi Nagar, Moradabad.

M/s East India Dressing Traders,
Kanth, Moradabad.

M/s E. P. I. Blema,
Kanth, Moradabad.

M/s Floner Surgical,
Mohalla Kanungoyan, Moradabad.

M/s Hindustan Drug House,
D-6 Industrial Estate, Moradabad.

M/s Indochem Surgical,
P. O. Kanth, Moradabad.

M/s Janta Blood Bank & Pathology,
Laboratory, Mordabad.

M/s Mayur Chemical & Pharmaceuticals,
Pilikothi, Mufli Tola, Moradabad.

M/s M. A. Weaving Co. Factory,
Kanth, Moradabad.

M/s Modern Surgical Trader,
Kanth, Moradabad.

M/s Racy Manufacturing Co.,
Joya, Moradabad.

M/s R. G. Chemical Works,
Gajraula Distt. Moradabad.

M/s Shakil Surgical, Kanth,
Moradabad.

M/s Upper India Surgical Dressing
Centre Mohalla Pirthiganj,
P. O. Kanth, Moradabad.

MUZAFFARNAGAR (DISTT.)

M/s Bharat Drug Industries,
Budhana Road, Khatauli, Muzaffarnagar.

M/s Dhaka Surgical & Chemicals Co.,
22/8 Gandhi Colony,
Muzaffarnagar.

M/s Eastern Surgicals, Patel Nagar,
New Mandi, Muzaffarnagar.

M/s Mahabir Sales Corporation,
12-A, Industrial Estate,
Meerut Road, Muzaffarnagar.

M/s Mascot Pharmaceuticals,
Patelnagar, Muzaffarnagar.

M/s Unitex Surgical Division,
New Mandi, Muzaffarnagar.

NAINITAL (DISTT.)

M/s Diamond Surgical
8-8, Pilikothi, Civil Line,
Haldwani, Nainital.

M/s Himalayan Product and Industries,
Nainital Road, Kathgodam, Nainital.

M/s Kapoor Industries,
Rampur Road, Haldwani, Nainital.

M/s Satya Vaccine Institute,
Patwadanager, Nainital.

RAMPUR (DISTT.)

M/s Jindal Surgical Industries,
Rampur.

SAHARANPUR (DISTT.)

M/s Amrit Pharmacy,
Rani Bazar, Saharanpur.

M/s Gypatone Industries,
Saharanpur.

M/s Handson Pharmaceuticals Manufacturing Corporation,
Tapri Station, Saharanpur.

M/s Himalaya Rock Chemical,
D-18 Industrial Area, Hardwar.

M/s Hindustan Chemical Industries,
Glea Colony,
Court Road, Saharanpur.

M/s Medico Laboratories,
Mission Compound, Saharanpur.

M/s Mumor Chemicals Industries,
B-153 Awas Vikash Parishad,
Delhi Road, Saharanpur.

M/s Popular Drugs & Chemical Audyogic Shakari Samiti Ltd.,
192, Rajputana Street, Roorkee.

M/s Shivalik Drug,
Kankhal, Hardwar.

M/s Sudha Pharmaceuticals,
Bhopatwala, Hardwar.

M/s United Pharmaceuticals,
53, Civil Lines, Roorkee.

SITAPUR (DISTT.)

M/s Ayur Pharma
Biswan, Sitapur.

M/s Swastic Surgical Dandi,
G. T. Road, Dulhipur Varanasi.

M/s Kapoor Pharmacy,
Arya Nagar, Sitapur.

UNNAO (DISTT.)

M/s Northern India Gas Co. Ltd.,
Industrial Area, Unnao,

M/s Rallis India, Magarwara,
Unnao.

M/s Rayhan Pharmaceuticals (P) Ltd.,
Village Sahganj, Unnao.

VARANASI (DISTT.)

M/s Aene Surgical Industries,
K-67/22 Ishwar Ganj, Varanasi.

M/s Asceptic Laboratories,
255, Jangambari, Varanasi.

M/s Ayurved,
Varanasi.

M/s Ayurved Sewa Asharma (P) Ltd.,
Mandiah, Varanasi.

M/s Bharat Chemical Industries,
S-19-40 Nai Bazar, Barna Bridge, Varanasi.

M/s Bharat Pharmachem, C-5,
Industrial Estate, Varanasi.

M/s Chemices Pharm,
D-47/4 Ramapur, Varanasi.

M/s Dic Laboratories,
E-13-14 Small Industries Estate, Varanasi.

M/s Doc Labs (P) Ltd,
9/81 Wasidpur, Ramnagar, Varanasi.

M/s Indian Air Gases,
Mugal Sarai, Varanasi.

M/s Industrial Gases, D/W,
Township, Varanasi.

M/s Kalinga Chemical Industries,
Dulhipur, Varanasi.

M/s Parijat Chemicals Works,
D-11 Industrial Estate, Varanasi.

M/s Paskays Pharmaceuticals,
Lanka, Varanasi.

M/s Peakays Pharmaceuticals,
Bhagwanpur, Varanasi.

M/s Prakash Chemical Industries,
Vill. Mahiya, P. O. Kusht Asharma, G. T.
Road, Varanasi.

M/s Raj Chemical Works,
Dulhijoo Road, Varanasi.

M/s Research & Development,
Industrial Biological & National Product &
Technical Services (P) Ltd, C-3 Big Industrial Estate, Chanipur, Varanasi.

M/s Sawastic Pharmaceuticals
G. T. Road, Dulhipur, Varanasi.

M/s Shri Ram Dhara Laboratories
Birdpur, Varanasi.

M/s Varanasi Chemical Company
J/12/140 Dhup Chandi, Chawkaghat,
Varanasi.

INDUSTRIAL LICENCES AND LETTERS OF INTENT

ISSUED DURING AUGUST, 1980

Sl. No.	Name and Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. & Date of Licence
	Licences				
			Name of Formulation		
1.	The General Manager, Indian Drugs & Pharmaceuticals Ltd. Hyderabad.	Hyderabad	1. Oxytetracycline Hydrochloride 2. Nutritional formula (Veterinary formulation) 3. Diazepam Injectable 4. Doxycycline 5. Doxycycline hyclate syrup		New Article IL: 59/80 dated 27.8.80
			Name of the Bulk Drugs	*Qty. Required (kgs)*	
			Vitamin A Acetate	1890	
			Vitamin E	90	
			Vitamin K	53	
			Calcium Pantothenate	470	
			Vitamin B_1 Mononitrate	105	
			Vitamin B_2	181	
			Nicotinamide	832	

Sl. No.	Name and Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. & Date of Licence
			Oxytetracycline	3470	
			Vitamin B_{12} (in gms)	378	
			Vitamin D_3 (in gms)	2347	
			Diazepam	25	
			Doxycycline HCl	1244	
			Doxycycline hyclate	486	
2.	Uni-UCB Pvt. Ltd., 22, Bhulabhai Desai Road, Bombay.	Maharashtra	Quimotrase injections (Ophthalmic preparation)	1,50,000 (2mg/Vial) 12,00,000 (5mg/Vial) 12,00,000 (50mg/vial)	New Article CIL: 212/80 dated 6.8.80
	Letters of Intent				
1.	Bengal Chemicals & Pharmaceuticals Ltd., 164, Manektala Main Road, Calcutta.	Calcutta	*Capsules*		Substantial Expansion LI: 423/80 dated 29.8.80.
			1. Amoxycillin	1250 kgs	
			2. Ampicillin	1000 ,,	
			3. Chloramphenicol	1250 ,,	
			4. Tetracycline	2500 ,,	
			Tablets		
			i. Co-trimoxazole (sulfamethoxazole/ Trimethoprim)	4000 ,, 800 ,,	
			2. Iron tablets with folic acid		
			Ferrous fumarate	1250 ,,	
			Folic acid	30 ,,	
			3. Iron tablets with folic acid & Vitamin B_{12}		
			Folic acid	30 ,,	
			Ferrous fumerate	1250 ,,	
			Vitamin B_{12}	100 gms.	

(Conrd.)

Sl. No.	Name and Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. & Date of Licence
			4. Magsil DMPS tablets		
			Magnesium hydroxide	6250 kgs.	
			Magnesium trisilicate	2500 ,,	
			Aluminium Hydroxide	6250 ,,	
			Simethicone	1250 ,,	
			5. Paracetamol	2500 ,,	Substantial Expansion LI: 424/80 dated 29.8.80.
			6. Chlorpropamide	1.2 tonnes (exist.) 12 ,, (after expn.)	
			7. Tolbutamide	1.0 ,, (exist.) 12 ,, (after expn.)	
			8. Nikethamide	0.6 ,, (exist.) 12 ,, (after expn.)	
2.	Ciba-Geigy of India Ltd., 17-J. Tata Road, Bombay.	Maharashtra	1. Trimethoprim	6 tonnes	New Article LI: 455/80 dated 30.8.80.
			2. Formulation of trimethoprim	2 tonnes in terms of bulk drug	
3.	Indian Drugs & Pharmaceuticals Ltd., P. O. Virbhadra, Rishikesh.	Rishikesh (U. P.)	*Bulk Drugs*		
			1. Dicloxacillin	15 tonnes	New Article LI: 425/80 dated 29.8.80.
			2. Amoxycillin	25 ,,	
			Formulation		
			1. Diclxacillin capsules		
			2. Amoxycillin capsules		
			3. Ampicillin trihydrate capsules		
			4. Gentamycin injection		

Sl. No.	Name and address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. & Date of Licence
			Name of Bulk Drugs Required	*Annual Cap. in Terms of Bulk Drug*	
			Dicloxacillin sodium	6.875 tonnes	
			Amoxycillin trihydrate	12.375 ,,	
			Ampicillin trihydrate	16.500 ,,	
			Gentamycin sulphate	0.220 ,,	
4.	Indian Drugs & Pharmaceuticals Ltd., Hyderabad.	Hyderabad	1 Multi Vitamins with 1 Minerals capsules/tabs		New Article LI: 433/80 dated 29.8.80.
			Name of the Bulk Drug Required		
			Folic Acid	0.025 tonnes	
			Pantothenate	0.210 ,,	
			Vitamin A Acetate	0.250 ,,	
			Pyridazine HCl	0.075 ,,	
			Nicotinamide	1.250 ,,	
			Vitamin B1 Mononitrate	0.250 ,,	
			Riboflavin	0.125 ,,	
			Ferrous fumerate	1.050 ,,	
			Vitamin D2 (gms)	0.320 ,,	
			Cyanocobalamin (gms)	0.465 ,,	
			Ascorbic acid	2.500 ,,	

(*Contd.*)

Sl. No.	Name and Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. & Date of Licence
			Formulations		
			2. Vitamin Oral drops		
			3. Vitamin premix-1		
			4. Vitamin A solution		
			5. Oral contraceptives		
			6. Ferrous Fumerate		
			7. Cough syrup		
			8. Sodium sulphadimidine		
			9. Oxyphenbutazone tablets		
			Name of Bulk Drug Required	*Annual Capacity in Tonnes*	
			Ascorbic acid	0.900 tonnes	
			Vitamin A Palmitate	2.100 ,,	
			Vitamin A acetate	2.100 ,,	
			Vitamin D3	33.400 (gms)	
			Vitamin A Palmitate	25.300 ,,	
			Ethinylestradiol	1.520 ,,	
			Norethisterone	0.051 tonnes	
			Ferrous Fumerate	0.966 ,,	
			Chlorpheniramine maleate	0.063 ,,	
			Sulphadimidine	15.600 ,,	
			Oxyphenbutazone	2.1000 ,,	
5.	Shri P. C. Mehta, Mehta Pharmaceuticals Pvt. Ltd., No. 2, Circular Road, Amritsar, Punjab.	Amritsar	Rutin (Vitamin P)	72 tonnes	New Articles LI: 442/80 dated 30.8.80

Sl. No.	Name and Address of the Industrial Undertaking	Location	Article of Manufacture	Annual Capacity	Type, No. & Date of Licence
6.	Pfizer Limited, Express Towers, Nariman Point, Bombay.	Maharashtra	1. Morantel tartrate 2. Pyrantel Pamoate	15 tonnes 30 ,, (after expn.)	Substantial Expansion LI: 383/80 dated 21.8.80.
			3. Formulations of the two drugs specified above	Upto 50% of each of the two capacities specified above	
7.	The Anil Starch Products Ltd., Anil Road, P. B. No. 1062, Ahmedabad.	Ahmedabad	Ascorbic acid (vitamin C) and its salts	250 tonnes	New Article LI: 458/78 dated 30.8.80

NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
1.	*Acne Treatment*			
	Meclocycline sulfosalicylate	Meclan	Ortho	USA
2.	*Analgesic*			
	Diflunisal	Dolobid	Merck Sharp & Dohme	S. Africa
	Dipipanone	Wellconal	Wellcome	Israel
	Floctafenine	Idarac	Roussel	Canada
3.	*Anorectic*			
	Mazindol	Mazildene	Farmochimica	Italy
4.	*Anthelmintic*			
	Oxantel pamoate+ pyrantel pamoate	Quantrel	Pfizer	Thailand
	Praziquantal	Biltricide	Bayer	W. Germany
5.	*Antiarrhythmic*			
	Ajmaline	Normortmina	Chemil	Italy
	Mexiletine	Mexitil	Boehringer Ingelheim	Thailand
6.	*Antibacterial*			
	Cefadroxil	Duricef	Bristol	Canada
	Cefamandole	Mandokef	Lilly	Thailand
	Cefoxitin	Cefoxin	Merck, Sharp & Dohme	Thailand
	Cinoxacin	Cinobac	Lilly	USA
	Josamycin	Josacine	Spret-Mauchet	Italy
	Pivampicillin	Pondocillin	Burgess	UK
	Ribostamycin	Ribostamin	Delalande	Italy
	Sisomicin	Ensamycin	Schering Corp	Thailand

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
	Spiramycin	Rovamicina	Carlo Erba	Italy
	Sulbenicillin	Sulbenil	Takeda	Netherlands
	Trimethoprim	Idotrim	Ferrosan	Sweden
	Trimethoprim	Wellcoprim	Wellcome	Sweden
	Trimethoprim-sulfamethoxazole (Co-trimoxazole)	Fectrim	DDSA	UK
7.	*Antidepressant*			
	Mefexamide	Mefexamide	Lipha	W. Germany
8.	*Antihyperlipidemic*			
	Niceritrol	Perycit	Sanwa	Japan
	Tiadenol	Tiaterol	Clin-Midy	Italy
9.	*Antihypertensive*			
	Guanfacine	Estulic	Wander	W. Germany
	Oxprenolol+ hydralazine+ chlorthalidone	Trepress	Geigy	W. Germany
10.	*Anti-inflammatory*			
	Feprazone	Zepelan	WB Pharmaceuticals	W. Germany
	Indomethacin	Artracin	DDSA	UK
	Orgotein	Orgotein	Gruenenthal	W. Germany
	Terofenamate	Etofen	Lusofarmaco	Italy
11.	*Antineoplastic*			
	Cisplatin	Abiplatin	Abic	Israel
	Cisplatin	Platinol	Mead Johnson	Philippines
	Etoposide	Vepesid	Bristol-Myers	France/ W. Germany
	Lomustine	CeeNU	Mead Johnson	Philippines
	Megestrol acetate	Megase	Mead Johnson	Philippines
12.	*Antirheumatic*			
	Aurothioglucose	Aureotan	Iromedica	Switzerland
13.	*Antiulcer*			
	Sucralfate	Sulcrate	Nordic	Canada

Contd.

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
14.	*Antiviral*			
	Methisoprinol	Metisoprinol	Newport	Brazil
	Methisoprinol	Viruxan	Sigma-Tau	Italy
	Vidarabine	Vira-A	Parke-Davis	Israel
15.	*β-Blocker*			
	Mepindolol	Caridian	Schering AG	W. Germany
	Oxprenolol	Trasicor	Ciba	Canada
16.	*β-Blocker/diuretic*			
	Metoprolol + Chlorthalidone	Lopresoretic	Geigy	UK
17.	*Bronchodilator*			
	Aminophylline	Phyllocontin	Purdue Frederick	Canada
	Fenspiride	Pneumorel	Servier	Thailand
	Theophylline	Neulin SR	Riker	Philippines
18.	*Calcium regulator*			
	Calcitriol	Rocaltrol	Roche	S. Africa
19.	*Cardiac stimulant*			
	Dobutamine	Dobutrex	Lilly	Sweden/ Thailand
20.	*Debriding agent*			
	Dextranomer	Debrisan	Pharmacia	Switzerland
21.	*Decarboxylase inhibitor*			
	Carbidopa	Menesit	Merck Banyu	Japan
	Carbidopa	Neo-Dopaston	Sankyo	Japan
22.	*Hypnotic*			
	Lormetazepam	Noctamid	Schering	W, Germany
	Lormetazepam	Loramet	Wyeth	W. Germany
	Triazolam	Halcion	Upjohn	Italy/Thailand
23.	*Muscle relaxant*			
	Glafenine + thiocolchicoside	Glifarelax	Roussel	Philippines

Sl. No.	Generic Name	Trade Name	Name of the Manufacturer	Country
24.	*Ocular corticosteroid/antibacterial*			
	Dexamethasone + framycetin	Cebefrasone	Chauvin-Blanche	Philippines
25.	*Peripheral vasodilatar*			
	Buflomedil	Loftyl	Abbott	Philippines
	Suloctidil	Duloctil	Searle	W. Germany
26.	*Respiratory stimulant*			
	Fominoben	Terion	Lusofarmaco	Italy
27.	*Topical antibacterial*			
	Mafenide acetate	Mafatate	Torii	Japan
28.	*Topical antifungal*			
	Tolciclate	Tolmicen	Carlo Erba	Italy
29.	*Topical corticosteroid*			
	Diflorasone diacetate	Florone	Upjohn	Thailand
30.	*Topical corticosteroid/antifungal*			
	Miconazole + hydrocortisone	Daktacort	Janssen	Philippines
31.	*Tranquilizer*			
	Clorazepate	Tranxene	Clin-Midy	Israel
	Pipotiazine palmitate	Piportil LA	Specia	Israel
	Minaprine	Cantor	Clin-Midy	France
32.	*Uterine relaxant*			
	Ritodrine	Yutopar	Merrell	USA
33.	*Vasodilator*			
	Suloctidil	Locton	Lepetit	Italy

BOOK REVIEW

WHO Expert Committee on Specifications for Pharmaceutical Preparations.

Twentyseventh Report—World Health Organization, Technical Report Series, No. 645, 1980. Pages 54, Price: Sw. fr. 4.-.

This publication is mainly devoted to recommendations on tests used for the quality control of solid oral dosage forms (such as tablets and capsules) and to a general review of drug quality control systems. A number of allied topics are also dealt with, including a progress report on the third edition of the International Pharmacopoeia, of which Volume 1 has already appeared. The current status of International Chemical Reference Substances is described, followed by a brief review of basic, simplified tests for establishing the identity of a drug and for ascertaining the absence of gross degradation to meet the needs of the many developing countries that do not have easy access to large, well-equiped drug control laboratories.

The report describes the test methodology to be used for tablets and capsules and includes a number of new approaches, especially in the testing of their strength and performance. The tests for strength are usually carried out by a simplified approach in a combined procedure consisting of the assay of a composite prepared from a number (usually 20) of tablets and then testing the uniformity of weight. In the case of highly potent drugs this is not fully reliable and a more complicated procedure (a "content uniformity test") has to be used. Performance tests are designed to provide assurance that the dosage form, when administered, will release the active ingredient as it is intended to do. Concerning these tests, the report gives details of standardized disintegration testing and advises on the approaches to be used for dissolution testing.

The report notes that the process of acquiring a pharmaceutical raw material, converting it into a finished product and making it available to the consumer involves a number of operations which require stringent surveillance to ensure that the user receives a satisfactory product. Countries have evolved a variety of procedures for quality assessment, and to aid the evolution of such national programmes the report provides, in an annex a comprehensive review of approaches to drug quality assessment and assurance. ☐

DRUGS AND PHARMACEUTICALS INDUSTRY IN UTTAR PRADESH

Though Uttar Pradesh is the most populated and one of the largest states in the country, the drugs and pharmaceuticals industry has not made much progress in this State. Uttar Pradesh lags behind Maharashtra, West Bengal, Tamil Nadu and Gujarat in drug industry and has a total of about 360 manufacturing units, most of which are in small—scale and medium-scale sectors. The total production of drugs in the state is worth Rs. 5 crores while the consumption is around Rs. 100 crores. This alarming gap in demand and supply will widen further during the sixth Five Year plan when demand reaches Rs. 200 crores with the proposed establishment of 100 primary health centres, 7000 sub-centres and 500 Ayurvedic centres.

Precisely, what are the reasons for the backwardness of the state in respect of the drugs and pharmaceutical industry? To find an answer to these problems a one day Seminar on "*Drugs & Pharmaceuticals Industry in UP: Problems and Prospects*" was held on 25 November, 1980 at Central Drug Research Institute, Lucknow. Sponsored by the State R&D Committee and organised by CDRI and Small Industries Service Institute, Kanpur, the seminar provided a common platform to entrepreneurs, industrialists, R&D scientists and Government policy makers for discussing problems faced by the industry in the State and suggesting remedial measures. The Seminer was inaugurated by the Minister of Public Health, UP, Mr. Lokpati Tripathi, and addressed by the Chief Minister of UP, Mr. Vishwanath Pratap Singh, as Chief Guest.

Of all the 22 papers (*See* the box) received for the Seminar only three dealt with the prospects for establishing new units while others highlighted problems faced by the industry-thus reflecting that problems faced by the industry are far too many. As pointed out by Dr. Nitya Nand, Chairman, State R&D Committee of UP and Director, CDRI, Lucknow, the UP manufacturers face strong competition from the large firms of other States due to lack of confidence among consumers in drugs made within the State. The confidence can be buildup if the State Drug Control Organisation ensures the quality of drugs produced in UP. However, this is possible only if this organisation is delinked from the Medical and Health Directorate and suitably strengthened. The Drug Controller should have atleast 126 technically qualified staff at various levels as against the present strength of 26 only. Dr. Nitya Nand suggested for the growth of the industry certain incentives, such as: (*i*) a package deal to entrepreneurs including registration, finance, licence and other facilities required; (*ii*) reduction of excise duty on molasses and alcohol; (*iii*) sales tax reduction from 8% to 5% to bring it at par with other states; (*iv*) Uninterrupted supply of power (*v*) preference in purchases of the State Government departments; (*vi*) rationalisation of production pattern to avoid unequal competition between the public and private sectors.

The Seminar was, thus, crucial in focussing attention on three vital aspects; (*i*) Problems of production, specially of essential drugs; (*ii*) Strengthening the drug control organization ; (*iii*) Promotion of small-scale sector. The recommendations made at the conclusion of the seminar are as under:

Drug Control Organisation:

An efficient and independent drug control organisation manned by qualified personal should be set up. The organisation should be decentralised in all the towns and districts. The grant of licences to the manufacturing units should also be decentralised and authority delegated at divisional level to avoid inordinate delays in the grant of licences.

Drug Advisory Committee:

A drug advisory committee should be constituted comprising of representatives from Government agencies, drug houses of private and public sectors, CDRI and other educational departments, financial organisations, etc. These members will go into all aspects of drug administration and drug manufacture to identify the problems and suggest the remedial measures.

The State R&D Laboratory:

A State R&D Laboratory should be established to help small-scale industry. This laboratory will generate appropriate technology for all the essential bulk drugs and their intermediates suiting the small-scale industry. It will also help in the purchase of quality drugs (after their rigorous testing in the laboratory) manufactured in the State for supply to the Government hospitals. The drugs supplied and tested by this laboratory should carry generic names only. The setting up of laboratory will encourage entrepreneurs to take up the production of drugs and to utilize the processes already developed in the national laboratories.

It will also introduce the prospective entrepreneurs to model small-scale formulation units involving different capital investments. The proposed laboratory will have a role in assimilation of the sophisticated technology already imported into the country and develop it further by organised research and development activities.

Essential Drugs and Intermediates:

Production of essential drugs and their intermediates as mentioned by the task force of Planning Commission should be taken up in an integrated manner by allowing expansion in formulation production. Naphtha produced from Mathura refinery, as and when it becomes operational, should be fully utilised by setting up plants for recovering aromatic chemicals like benzene, toluene, xylene etc. This will help in the production of a large number of intermediates.

Phytochemical Complex:

A Complex for the production of phytochemicals should be set up because most of the plants used in modern medicine can be cultivated in one or the other regions of the State. Proper utilisation of this resource could be developed into one of the most important industry, and being linked with cultivation it offers immense employment potential.

Utilisation of By-Products:

The products obtained from agro-waste, petro-chemical complex, ethanol and slaughter house by-products should be utilized to produce intermediates required for the manufacture of drugs. These units should serve as ancillaries to the bulk manufacturers.

Small-Scale Sector:

Production of formulations, especially the tableting and capsuling should be confined to the small-scale industry, while the injectables and transfusions should be taken up by large industrial houses either in private or in public sectors. Manufacture of heavy organic and inorganic chemicals which are the backbone of the drug industry, should be taken up by large industrial units in the state.

Drug Purchase Policy:

In order to encourage the manufacturers in the State, especially those in the small-scale sector, the Health Department of Uttar Pradesh should be liberal in purchasing quality drugs from them.

Pharmacy Education:

Pharmacy education is inadequate in the State. Kanpur Medical College offers a certificate course in pharmacy and graduation and postgraduation facilities are available only at Banaras Hindu University, Varanasi. A school of pharmacy should, therefore, be established in the State preferably at Lucknow.

Power Supply:

Interruptions or failures of power supply cause enormous losses to the industry. Sometimes entire batches have to be discarded, resulting in increased production cost. The industry should be ensured uninterrupted supply of power and be exempted from power cuts.

Alcohol:

Alcohol is one of the most important and essential raw materials for the drug industry. It is, therefore, suggested that the procedure for grant of alcohol quota to a drug unit should be made simpler. Alcohol being used in drugs production, should be exempted from excise duty.

Taxation:

Drug industry should not be subjected to multi-step taxation. It should be given relief in taxation especially in the sales tax which should be reduced from 8% to 5% as has been done in other states. The local taxes may also be reduced. The relief in taxes will not only give incentive to the industry but will also reduce the cost of the drugs.

Of Sessions and Speakers :

The seminar was spread over three technical sessions. First session was chaired by Mr. A. C. Chaturvedi, Secretary Dept. of Science & Technology, Government of U. P. and had key-note addresses by Dr. Akhtar Husain, Director, CIMAP on "*Prospects of Establishment of Plant-Drug Industry in Uttar Pradesh*" and by Dr. S. K. Chatterjee, Assistant Director, CDRI on "*Pharmaceutical Industry in U. P., Requirements and Resources*". The other speakers in this session included: (*i*) Dr. Naseem Zaidi, Dy. Secretary to Chief Minisitar, U. P. on "*Potential of Drug Industry in U. P.*" and (2) Dr. V. S. Mathur, Associate Professor Pharmacology, PGIMER, Chandigarh on "*Quality Drugs at Reasonable Cost*".

The second session was chaired by Mr. S. C. Tripathi, Managing Director, PICUP and the key note addresses were delivered by Dr. B. S. Bajaj, General Manager, IDPL, Rishikesh on "*D&P Industry in Uttar Pradesh-Problems and Prospects-with special reference to IDPL, Rishikesh*" and by Mr. V. A. K. Saxena, of G. Proxen & Company on "*Drugs and Pharmaceutical Industry in U. P.—Problems*". The others who read papers in this session were: (1) Mr. Girish Chandra Jain, Proprietor, Kotia Drug House, Agra on "*The Role of the Licensing Authorities and Financial Institutions in the Development of Pharmaceutical Small-Scale Units in Uttar Pradesh.*"; (2) Mr. Satish Ahuja of Saharanpur on "*Problems in Setting up a Pharmaceutical Unit with Government Financial Assistance.*" (3) Dr. V. N. Puri on "*Drugs of U. P. in Private Practice of Medical Profession.*"; (4) Dr. (Miss) Geeta Devi, U P. D. P. L. Lucknow on "*Drugs & Pharmaceuticals Industry Some Relevent Problems;* (5) Mr. Bal Krishnan Agarwal on "*Impractical Aspects in Drugs and Cosmetics Act and Their Effects on the Daily Working*"; (6) Mr. Harish Mehrotra, Arun Udyog, Kanpur on "*Inclusion of Phenyl and Epsom Salt in Drugs and Cosmetics Act—An Anomaly*".

The concluding session was chaired by Mrs. Lata Singh, Commissioner and Secretary, Family Welfare, Government of U. P. and its key note speakers were Dr. Surendra Rohtagi, of Hind Chemicals, who spoke on "*Drugs Administration and Pharmacy Education in the State*" and Dr. I. K. Kacker, of K. Methaqualone and Chemicals Pvt Ltd. on "*Development of Drugs and Pharmaceutical Industry in U. P. : Some Suggestions.*" Mr. R. S. Bhargava, of Labors Chemical spoke on "*U. P. Pharmaceutical Industry and Government Purchase Policy.* The concluding remarks were made by Dr. A. C. Roy, Chairman Organising Committee.

DRUG INDUSTRY

General News

Revised prices for formulations soon

Union Minister of Petroleum, Chemicals and Fertilizers, Mr. P. C. Sethi informed Lok Sabha that BICP (Bureau of Industrial Costs and Prices), would shortly announce the revised prices of formulations made from the 14 bulk drugs which have been granted a price rise, a few days back (*See* Question No. 1119, p. 407). BICP has been further asked to announce the revised prices of 62 bulk drugs based on raw materials costs as on 31 August 1980.

The minister also expressed his willingness to have a fresh look at the drug policy of 1979 with the aim of increasing production of life saving and other essential drugs. He said that a new mechanism would be devised to link the prices of drugs with prices of the basic raw materials so that BICP need not be approached, whenever prices of raw materials went up.

Drug shortages to be monitored

The Ministry of Petroleum and Chemicals will, henceforth, monitor reports regarding shortages of essential and life saving medicines, so as to take necessary and quick remedial measures. Shri O. K. Rao, Assistant Development Commissioner (Drugs) has been authorized to receive complaints about the shortage of drugs.

Any complaint or problem about the drugs can be written directly to Assistant Development Commissioner (Drugs), Department of Chemicals, Shastri Bhavan, New Delhi or to the State Drugs Controller of the concerned State or to the Deputy Drugs Controller (India) based at Central Drugs Standard Control Organisation at Bombay, Calcutta, Madras or Ghaziabad.

India to export chemicals and pharmaceuticals to Hungary

India would export over 36 items relating to chemicals, drugs and pharmaceuticals to Hungary under a protocol signed by Dr. Charanjit Chanana, Union Minister of State for Industries and Madam E. Kesuru, Hungarian Minister of Light Industries at New Delhi. The protocol was signed at the end of fourth session of the Indo-Hungarian Joint Commission.

Both sides have agreed to explore the possibilites of setting up of joint ventures in India for the production of pharmaceutical formulations and steroid hormones. Hungary has agreed to supply chloramphenicol and chloroquin phosphate.

Pharmaceuticals export up during April-October 1980

The export of basic chemicals, pharmaceuticals and cosmetics during April-October 1980 increased by 30 per cent at Rs. 114.08 crore from Rs. 86.9 crore achieved in the same period last year. Of this figure, drugs, pharmaceuticals and fine chemicals' export was Rs. 45.37 crore compared to Rs. 36.41 crore in the same period, previous year. Export of basic inorganic chemicals, organic chemicals and agro-chemicals recorded an impressive 80 per cent increase in this period at Rs. 18.85 crore from Rs. 10.49 crore for the corresponding period of the previous year. Crude drugs export almost doubled, by 80 per cent, in this period compared to same period, last year.

Regularisation of excess drug capacity runs into difficulty

Two separate decisions of the Union Government have come in way of regularisation of excess drug capacities of the drug units. Government had announced in August that installed capacity will be regularised irrespective of licenced capacity, but the New Drug Policy statement of 1978 clearly says that regularisation will be done on highest production actually achieved in any year during the three year period ended March 31, 1977.

The salient features of the 1978 policy statement relating to drug capacity are;

(*a*) Units expanding beyond licenced capacity or contravening any condition attached with a specific licence will face punitive action;

(*b*) For foreign companies regularisation beyond licenced capacity will be done, subject to (*i*) their making available 50% of their excess bulk drug production to non-associated formulators; (*ii*) restricting the value of their formulations to five times the value of total bulk drug production;

(*c*) For Indian, public sector and MRTP companies, regularisation of excess production will be done on the condition that they make available 30,40 and 50% of their total production respectively (including regularised) to non-associated formulators and further restrict the production of formulations to 10 times the value of their bulk drug production;

(*d*) Excess production in decontrolled category will not be regularised;

(*e*) Excess production in household remedies produced by foreign sector will not be regularised; and

(*f*) Excess production in any category will be regularised if the company undertakes to export such excess for a period of five years.

However, these procedures, and many more, have not yet been notified. Now the Industrial Policy Statement made in August says that automatic growth would be allowed for drug intermediates required for the production of high technology bulk drugs from basic stage and the formulations based there up on with an overall ratio of bulk drug consumption to formulation production being at 1:10. This is not keeping in line with the 1978 statement. So industry wants this issue to be resolved before proceeding for regularisation of excess capacities.

57 drug licence applications rejected during 1977-79

During the period 1977-79, Government has rejected 57 applications submitted by various pharmaceutical companies. As many as 15 different reasons were cited for rejection of these applications. The various reasons are:

1. Already existing capacity not fully utlised.
2. Quotas already approved for the particular drug.
3. Lack of clearance under MRTP act.
4. Applicant did not possess requisite know-how for the drug.
5. Item reserved for public sector/small-scale sector.
6. Poor record of applicant with previous industrial licences.
7. Applicant not fully conversant with relevant technology.
8. Manufacturing process not fully developed by the company.
9. Collaboration proposal not finalised.
10. Proportion of imported raw material too high.
11. Stipulated bulk/formulation ratio not satisfied.
12. Item not approved/falling under the Drugs and Cosmetics Act.
13. Bulk drug not being manufactured from basic stage.
14. Demand for item satisfied by small-scale sector.
15. Proposed plant location not conforming to prevalent Government policy.

Drug shortages: Remedial measures taken

Of late the reports about the scarcity of life saving drugs and formulations from New Delhi, Calcutta, Madras and Bombay have appeared in newspapers. These mostly pertain io drugs being used in hypertension, leprosy, dysentery and pre- and post delivery cases. Shortages of chloromycetin, streptomycin, paediatric and vitamin formulations have also been reported. Not all the drugs of these categories are in short supply but only a few particular brands, according to the concerned sources. Of course, the equivalent formulations in all such cases are available and are being rushed to the places from where such shortages are being reported.

Of the 27 major pre-and post delivery formulations, periodic shortages of syntocinon injections and methergin both produced by Sandoz and pitocin by Parke. Davis have been reported. Labour unrest and capacity constraints are the factors responsible in case of Parke Davis product. However, an equivalent formulation, unitocin by Unichem is easily available.

In the case of drugs used in hypertension and high blood pressure, out of about 30 major formulations, shortages of only five, adelphane tablets and adelphane esidrex both of Ciba-Geigy, aldomet of MSD, emdopa of IDPL and meldopa of Dey's Medical Stores, have been reported. Labour unrest in all the above cases has been responsible for the short supply. As for the other drugs, equivalent formulations were available and their manufacturers were asked to rush supplies to scarcity areas.

Dapsone, the leprosy drug, was reportedly in short supply at Madras and Bombay. Burroughs wellcome, the largest manufacturer of this drug cited power cuts and capacity constraints as the reasons for short supply. Similarly, out of 18 formulations of dysentery medicines only two, enteroquinol of East India and thalazole of M&B were in short supply, though equivalents were available. IDPL has now agreed to provide the basic drug phthalyl sulphathiazole to M&B. This will help in overcoming the shortage.

Cancer drug: Government insists on introduction under generic name

The Central authorities have stalled the introduction of a new single ingredient drug 'Nolvadex' because of its insistence for introduction under generic name in accordance with its latest guidelines and as stipulated in Hathi Committee recommendations. This durg being introduced by Indian Chemical Industries is for the treatment of breast cancer.

Nobel prize for three in medicine

Three scientists will share this year's Nobel prize for medicine. They are Prot. F. Jean d' Ausset of the Immunology and Hematology Laboratories of the University of Paris; Prof. Baruj Benacerri of the Pathology Department of Harvard Medical School, Boston and Prof. George Snell of the Jackson Laboratory, Bar Harbor, Maine, USA. They have been chosen for their discoveries about genetically determined cell surface structures that regulate immunological reactions.

Industry wants Government to announce leader prices

The Government has recently revised the prices of 14 bulk drugs based on 1979 raw materials prices as an interim measure to help the public seetor companies to overcome their financial crisis. However, it has, so far, not announced leader prices for formulations based on these drugs. In the absence of leader prices the drug industry both in public, and private sectors is unable to revise the prices of formulations.

There are more than 200 formulations based on these drugs. Since the bulk drugs will cost more now, the formulations price has to be revised accordingly. But Government's delay in announcing leader prices, has led to these formulations not being marketed, which will eventually lead to shortage of these drugs in the market. Industry sources want that Bureau of Industrial Costs and Prices, the agency reponsible for this, should declare leader prices as soon as possible to tide over a difficult situation.

World news in brief

Brazil: Inflation is taking its toll everywhere-Pharmaceutical Industry is no exception. And now the Brazilian industry has proved it by making a formal request to Government for an 85 per cent price hike.

Spain: Compared to Brazilian demand, the Spanish industry asked for just 32 per cent increase in prices. But what they got is a mere 13 per cent. Industry has promptly dubbed this price hike as a sure way to 'bankruptcy'.

Australia: This Government acted very wisely and instituted an enquiry—the Ralph enquiry—which, it is reported, has recommended a price increase of little more than 8 per cent.

Now with all these high prices and still clamouring for more, a strong sense for cutting down imports has also dawned in. Zimbabwe is introducing import controls to support its local industry. Incidently, the local pharmaceutical industry was established in times when almost all the countries had imposed trade embargo on Zimbawe thenknown as Rhodesia, a regime practising apartheid.

Thailand is also bidding to cut down its imports, currently amounting to about $ 20 millions. One of the local drug companies, the Thailand Pharmaceutical Co. Ltd. will be setting up a plant with Rumanian help to produce analgesics.

Iraq, has its own problems. Its Ministry of Health has stipulated that Chemical-Biological laboratories must be set up, with in six months, at every manufacturing plant "with the utmost sense of priority". Defaulters, will have to, of course, shut down the plant.

ABPI News, No. **182,** 5 (Nov. 80)

Cefamezin the top selling medicine in Japan

An antibiotic preparation Cefamezin of Fujisawa Pharmaceuticals is occupying the top position among all the medicines in Japan with a monthly sale of γ3600 million. Second place goes to Krestin (monthly sale γ2900 million), an anti-malignant tumour agent from Sankyo.

Antibiotic preparations numbering 33, were the maximum in the top 100 brands. Vitamin preparations, cardiovascular agents, and anti-inflammatory and analgesic preparations also formed the major groups.

Japan Medical Gazette, **17,** 1 (20 Nov. 80)

WHO to provide prescribing information on essential drugs

World Health Organisation's Expert Committee on the Selection of Essential Drugs is expected to finalise the decision about providing prescribing information for each of the drugs contained in the model list of essential drugs, when it meets for the third time in 1981. This step is expected to improve and rationalise the use of essential drugs.

Scrip, No. **529,** 11 (6 Oct. 80)

Effective US patent life on new drugs lowest in 1979

According to Dr Martin Eisman of the University of Rochester's Centre for the Study of Drug Development, the average effective patent life on the 13 new drugs approved by US Food and Drug Administration during 1979 was only 9.5 years, the lowest since 1966.

Following table gives the year-wise figure:

Year	*Patented New Chemical Entities*	*Average effective patent life*
1966	10	13.6
1967	16	14.4
1968	10	13.5
1969	8	12.7
1970	14	14.4
1971	12	12.2
1972	6	10.9
1973	12	12.1
1974	15	13.0
1975	11	11.4
1976	15	11.3
1977	15	9.6
1978	14	10.5
1979	13	9.5

Scrip, No. **542,** 10 (19 Nov 80)

UNIDO estimates 1980 world pharmaceutical production at $83,530 million

"Global Study of the Pharmaceutical Industry" a recently published document by UNIDO has estimated the world production of pharmaceuticals in 1980 to be at $83,530 million. Of this, the share of developed nations is 88% i. e. $73,970 million and rest is contributed by developing nations (12%, $9,560 million). The estimated value of world pharmaceuticals production for the years 1980, 1985 and 1990, both for developed, as well as developing regions is as follows:

Region	Estimated production in $ billion		
	1980	1985	1990
Developed			
North America	18.60	29.95	Not estimated
W. Europe	27.44	44.19	,,
Eastern Europe	15.96	25.70	,,
Others	11.97	19.27	,,
Total	73.97	119.11	175.01
Developing			
Africa	0.47	0.82	,,
Asia (Excl. China)	4.69	8.26	,,
Latin America	4.40	7.75	,,
Total	9.56	16.83	33.85
Developed regions %	88	87	84
Developing regions %	12	13	16
World Total	83.53	135.94	208.85

The study has taken an annual growth rate of 9% over 1977 levels for calculating 1980 estimated production. For 1985 figures, the annual growth rate taken into account is 10% for developed and 12% for developing regions. Similarly the rates are 8% and 15% respectively, for developed and developing regions for 1990 figures.

The study further reports the consumption pattern of some selected essential drugs over a five year period, 1980-85. This gives share of developing regions as well, as listed below:

Drug	Share of Developing Region in 1985	1980		1985	
		Quantity in MT	Value (in $ million)	Quantity in MT	Value (in $ million)
Acetylsalicylic acid	28	34,500	104	40,000	176
Amoxicillin	37	715	93	1,050	158
Ampicillin	40	2,840	215	3,300	280
Ascorbic acid	0.8	36,000	415	48,000	675
Benzylpenicillin	4.6	8,950	285	11,350	435
Chloroquine	100	1,200	42	1,500	63
Furosemide	21.8	170	13.6	220	25.3
Hydralazine	—	67	7.4	95	13.8
Hydroxycobalamine	31.6	6.5	49	9.5	52
Paracetamol	20	10,750	70	12,500	98
Piperazine	1.1	17,000	68	24,000	130
Reserpine	—	1.4	0.5	0.8	0.3

World pharmaceutical market DM 287,900 million in 2000: Hoechst forecast

Pharma division of Hoechst Pharmaceuticals has predicted a growth rate of 177% in the world market for human pharmaceuticals taking 1980 currency values and selling prices as the base. The following table gives the growth from the year 1980 to 2000:

Year	*Market Value (DM in millions)*
1980	103,900
1985	136,200
1990	174,100
1995	223,800
2000	187,900

Scrip, No. **540,** 10 (12 Nov. 80)

IFPMA assembly calls for government industry cooperation

The International Federation of Pharmaceutical Manufacturers' Associations had its tenth assembly in Madrid (Spain) in October. The assembly which had the main theme "The Pharmaceutical Industry's Contribution—Present and Potential—to World Health" was divided into three panel sessions namely scientific, economic and governmental dimensions.

The assembly emphasised that pharmaceutical industry has a major contribution to make to the health of the developed and developing nations, both in scientific terms through innovative research and in economic terms by helping to control health costs and by strengthening national economies. But this all needs active governmental cooperation by having right legislative framework to allow the industry to operate successfully.

The discussions in the economic session centered around how best industry could help in terms of, (*a*) the lowering of drug prices, especially on patent expiry and by competition until they are finally offered at almost marginal costs; (*b*) the development of innovative drugs with a more favourable cost-benefit ratio; (*c*) the use of cost-effective medicines to replace labour-intensive professional care and capital intensive equipment; and (*d*) its contribution to the economies of industrialized nations and the solution of health problems in the Third World.

In scientific session most of the participants agreed that from a pharmacological view-point the prospects for therapeutic advances were extremely bright. But now probability of achieving a breakthrough, by random screening of chemical compounds, was very low.

In the third session on industry-governmental relations, both the viewpoints were presented. Factors contributing to tense relations were identified namely; drug pricing, drug safety and profit making.

Similarly many participants discussed at length the ways and means of helping the Third World countries.

Scrip, No. **534,** 8 (22 Oct. 80)

Company Reports

CPC earns Rs. 1.75 crore in 1979-80

According to some reports, the State Chemicals and Pharmaceuticals Corporation of India, a subsidiary of State Trading Corporation, has earned a profit of Rs 1.75 crore for the year ended March 1980. This is 6.7% more, over the figures of previous year. The total income of the corporation amounted to Rs 137.4 crore, an increase of 26.3% over the previous year.

HAL aims at Rs. 100 crore turn-over by 1983-84

By 1983-84 the overall turn-over of the State owned Hindustan Antibiotics Ltd. is expected to go up to Rs. 100 crore, according to Sh. Y. H. Gharpure the Managing Director of the concern. This output takes into account the expected turn-over of the HAL participated three joint sector formulation units, being set up at Bangalore, Goa and Nagpur. Pimpri plant alone is expected to reach Rs. 65 crore level by that time compared to present Rs. 21 crore.

Attributing the recent losses to unremunerative prices, obsolete machinery and lack of diversification, the managing director said that a marginal profit is expected in 1981-82. Penicillin capacity is being doubled to 200 MMU from present 105 MMU. Similarly, streptomycin capacity will go up from 85 tonnes to 180 tonnes and ampicillin from 5 tonnes to 35 tonnes.

Old and obsolete machinery will be replaced at a cost of Rs. 12 crore. These measures, Mr. Gharpure says, will help HAL in overcoming the past losses and will ensure a smooth and profitable future sailing.

Glaxo pays 16% dividend

Glaxo Laboratories has recommended a final dividend of eight per cent on the expanded capital for the year ended June 1980. This combined with an interim dividend of eight per cent comes out to a total dividend of sixteen per cent.

Although sales have recorded a increase of more than 7 crores, from Rs. 73.55 crore to Rs. 80.84 crore, the gross profit has remained almost same, i.e., Rs. 11.48 crore for the period under consideration and Rs. 11.06 crore for the year before. Company management attributes this erosion in profit to rampant inflation and static and stagnant prices. The company has provided Rs. 1.1999 crore for depreciation, Rs. 65 lakhs for investment allowance, and Rs. 5.46 crore for taxation. Net profit left after this is substantially higher at Rs. 4.1692 crore compared to Rs. 3.4759 crore for the preceding year.

Glaxo workers, management dispute settled

An agreement valid for four years from July 1979 to June 1983, has been signed between the management of Glaxo Laboratories and the its employees' union. The agreement covers the overall terms and working conditions of the workers employed at Worli and Thane factories of the company. The company production in the past, was constantly suffering from industrial disputes and other labour problems.

Richardson Hindustan profits up by 69%

For the year ended June 1980, Richardson Hindustan Ltd. has achieved a gross sale of Rs. 16.56 crore which is 24% more compared to preceding year. Gross profits were Rs. 1.98 crore, an increase of 69% over last year.

Sunil Synchem to pay 8 per cent dividend

Sunil Synchem has decided to pay a dividend of 8 per cent to its share holders for the year ended April 30, 1980. The company made a net profit of Rs. 9.64 lakhs compared to Rs. 5.5 lakhs for the previous year. Its methyldopa plant is expected to go on stream very soon. The expansion of capsules and pharmaceutical plants is likely to enhance the future profitability.

Abbott to dilute

The wholly owned Indian subsidiary of Abbott Labs of US, the Abbott Laboratories (India) Pvt. Ltd., is planning to reduce its foreign equity holding to 40% as required under the New Drug Policy. The company has also planned to issue shares worth Rs. 1.35 crore. Of these, public financial institutions, will get Rs. 89 lakh worth of shares and the rest will go to public and employees of the company. The company has been granted permission to expand its capital on condition that it will undertake the manufacture of bulk drugs. Abbott has already got a "Letter of Intent" to manufacture six bulk drugs (*See*, Question No. 317, p. 404).

Joint sector aspirin, salicylic acid project proposed in W. Bengal

West Bengal Pharmaceutical and Phytochemical Development Corporation, West Bengal Industrial Development Corporation and a Maharashtra drug firm have proposed to set up a unit in joint sector for the production of salicyclic acid and aspirin. The necessary know-how will be supplied by some foreign multinational, probably a Japanese firm. The estimated annual capacities will be, salicylic acid 800 tonnes and aspirin, 1000 tonnes. Other products to be manufactured are *O*-nitrobenzene, 1100 tonnes ; *p*-nitrobenzene, 2,500 tonnes; dinitrobenzene, 800 tonnes and dinitrochlorobenzene, 300 tonnes.

Public sector drug units sales go down

According to the annual report of the Ministry of Petroleum, Chemicals and Fertilizers, the net sales of the five public sector drug concerns in 1979-80 was Rs. 103.4 crore compared to Rs. 103.7 crore for 1978-79. The sales for both the periods were as under:

Name of the Concern	*Sales* *1978-79* *Rs. in lakhs*	 *1979-80* *Rs. in lakhs*
State owned		
IDPL ..	7300	6830
Hindustan Antibiotics Ltd. ..	1620	1710
State Controlled		
Bengal Chemicals & Pharmaceuticals Works ..	690	800
Bengal Immunity ..	250	420
Smith Stanistreet ..	510	580

The figures show a decrease of 0.3% in 1979-80 from 1978-79 sales.

Research and Development

Improved drug delivery system: Dabur tie-up with US Corporation

Inter-X Corporation a research based organisation in the US may tie-up with Dabur industries for the production of improved drug delivery systems. Newer drug delivery systems avoid wastage of the drug substance which is so common in the conventional system of drug delivery. These methods are based on the controlled release of the drug substance in the body using the devices like osmotic pump, double osmotic pump and other sustained release dosage forms.

Cimetidine helps hirsute women

According to a study reported in *New England J. Medicine*, (p. 1042, 30 Oct. 1980), Cimetidine has been found to be a safe and effective treatment for and rogen dependent hirsutism. A small clinical trial was conducted by Dr. Robert Vigersky and colleagues, on five severely hirsute women. Cimetidine 300 mg was administered five times daily for three months and its effect assessed through measurement of hair growth.

The drug produced a decrease in hair growth and also lessening of the oiliness of skin and ache was observed. Cimetidine may be acting by way of blocking androgen action by inhibiting binding of dihydrotestosterone to androgen receptors. No galactorrhoea or abnormalities of liver, renal or haematologic function were noticed.

Scrip, No. **540**, 11 (12 Nov. 80)

Triazolam found to be an ideal hypnotic

In a study conducted over a group of patients, triazolam has come out with excellent results. All the patients were given 1 mg triazolam daily for six months and most of them are still using it, even after one year. Although this dose is quite high but has the beneficial effects since it; (*i*) induces sleep rapidly, usually within 30 minutes; (*ii*) maintains steady sleep with no increase in nocturnal awakenings over 1 year; (*iii*) does not change normal dreaming activities; (*iv*) keeps the patients alert when they awake; (*v*) has no side-effects.

The lack of tolerance to a 1 mg dose may also apply to the 0.25 mg and 0.5 mg doses which are more commonly used in ambulatory patients having no previous hypnotic experience.

Inpharma, No. **261,** 10 (1 Nov. 80)

Dose related study for chlorpromazine

Reports, though unsubstantiated, that doses of drugs such as chlorpromazine should be as low as half in various tropical countries compared to those used in European countries without any loss of therapeutic effects, will form the subject of a project to be undertaken by WHO. The project will consist of three interrelated studies: the dose effects of antidepressant medication; the dose effects of antipsychotic medication and the effects of benzodiazepines and therapeutic counselling. Apart from Bombay and Lucknow, the study will be undertaken at other collaborating centres of WHO at Basel (Switzerland), Cali (Colombia), Nagasaki and Sapporo (Japan), Nashville (USA), London (England) and Ibadan (Nigeria).

Scrip, No. **528**, 9 (1 Oct. 80)

Lilly starts human insulin trials in UK

Eli Lilly has started the clinical trials of the new biosynthetic human insulin in Britain. Biosynthetic human insulin is identical to that produced naturally in the human body by pancreas. West Germany and Greece are the other two countries participating in clinical trials.

According to the company sources much scientific work has to be done before supplies of the human insulin became available commercially.

ABPI News, No. **182,** 5 (Nov. 80)

Amoxapine, a rapid acting antidepressant

The demethylated metabolite of loxapine, amoxapine, is the latest tricyclic antidepressant which has been given approval in USA by Food and Drug Administration. It has been found to absorb quickly after oral administration and metabolizes to 7-and 8-hydroxyamoxapines having a half-life of 30 hrs which makes it once daily dose drug. Steady state levels are reached in 2 days for the drug and in 1 week for its metabolite.

Amoxapine has proved effective in endogenous, neurotic and reactive depressions as well as, in anxious, agitated, retarded or apathetic depressives. Its role is doubtful in schizophrenia, schizoaffective disorders and chronic melancholia.

Amoxapine therapeutic doses vary between 50 and 600 mg/day mostly, 200-300 mg/day being the usual dose, but to begin with it should be 100-150 mg/day increasing rapidly if needed and tolerated. The main dose is taken at night to avoid day time sedation. Once depression is controlled the dose can be reduced slowly but abrupt withdrawal is best avoided.

Inpharma, No. **263**, 2 (15 Nov. 80)

Propranolol interacts with chlorpromazine in schizophrenia

Reports suggesting that propranolol is of benefit in schizophrenia have usually involved patients taking concomitant neuroleptic treatment. This raises the possibility that the drug may be potentiating neuroleptics rather than having an intrinsic antischizophrenic action. To verify this, plasma levels of chlorpromazine—a neuroleptic-were measured in a group of patients who took chlorpromazine alone and with propranolol in a randomised trial. It was found that plasma levels of chlorpromazine and active metabolites were significantly increased during treatment with propranolol. Nature of interaction is not clear and these results can not be applied to other neuroleptics.

Lancet, **2,** 978 (1980)

Dezocine, a narctic analgesic for cancer patients

Significant pain relief was observed in cancer patients when given 10 mg of dezocine (WY 16225, Wyeth) *im* to 20 hospitalized patients with chronic pain from advanced cancer. 17 patients had better relief, 11 of them significantly, with dezocine compared to 3 on placebo. The effect lasted for a minimum of 4 hrs. Nausea was reported in seven patients.

Inpharma, No. **260,** 7 (25 Oct. 80)

Vaccine against Hepatitis-B virus developed

A large group of homosexual men, who are much prone to hepatitis B virus infection, were given inactivated hepatitis B vaccine in a placebo-controlled, randomized double blind study. Within 2 months of vaccination there were high levels of antibody against the hepatitis B surface antigen in most (77%) of those treated. After giving booster dose it increased to 96%. Even after first 18 months, hepatitis B or subclinical infection was minimum in the treated patients. Results from various other angles suggest the vaccine to be remarkable safe.

New England J. Medicine, **303,** 833 (9 Oct. 80)

DMSO dangerous in arthritis

US Food and Drug Administration, in a recent statement, has said that there is no generally acceptable evidence that Dimethylsulphoxide is safe or effective in treating arthritis or bursitis. Also, eventhough it has been tested for a number of disease conditions like genital herpes and mental retardation, its effectiveness is still not been proven. Similarly, a team of doctors at the Royal Free Hospital, London have concluded that "intravenous" DMSO is potentially dangerous and should not be used for the treatment of arthritis. The doctors had monitored two elderly patients treated with intravenous infusion of DMSO.

Both patients had shown biochemical changes with raised concentration of liver and muscle enzymes and evidence of haemolysis. One remained well but the other had serious complications like scantiness of the urine, transient loss of consciousness and an apparent cerebral infraction. DMSO, because of its strong attachment to plasma proteins could not be removed by peritoneal dialysis. It took five days for both the patients to recover.

Pharmaceatical J. **225,** 625 (29 Nov. 80)

Interferons-a plethora of information reported

At the First Annual International Congress for Interferon Research, which took place in Washington in November this year, a great amount of information was presented and still a number of baffling questions were left untackled.

According to the studies, presented at the Congress, there are a number of different species of interferons representing a vast variety of structures, properties and targets. And it is not clear which species attack which target and how best they can be delivered. Dr. Charles Weissman of Zurich told the Congress of a variety of interferons, some of which share a number of amino acids and others none, possibly each having a different cell activity. According to Dr. Weissman, various species can be reproduced in *E. coli*, i.e., via recombinant DNA. Moreover, interferon activity grows along with batch and can be propagated over hundreds of generations without losing its potency.

PMA Newsletter, **22,** No. 45, 1 (17 Nov. 80)

Metronidazole, a single dose regimen sufficient

In a double blind randomised trial, a single dose of metronidazole was found to be as effective as the standard seven day course (250 mg three times a day) for treating vaginal trichomoniasis. In 86 per cent of the women given 2g dose and in 91 per cent of the women given seven day course symptom duration and side effects did not differ significantly. But vertigo and headache were reported in patients in 2g group.

Although 2 g dose is cheaper and easier to administer, still more studies on its safety and efficacy are needed, according to the workers.

J. American Medical Association, **244**, 1219 (1980)

Metronidazole: the pros and cons

Metronidazole, much used against *Trichomonas* infection and amoebiasis, is found to be effective against giardiasis, non-specific vaginitis and anaerobic infections. It is bactericidal against nearly all obligate anaerobes except *Actinomyces*, *Arachnia* and *Propionibacterium*. The drug has been recommended to be used as follows:

(1) It should be used only for established indications, i.e., trichomoniasis, amoebiasis etc;

(2) The smallest dose that is effective for the shortest time should be used;

(3) It should not be used in the first trimester of pregnancy and should be avoided if possible in the last 2 trimesters and during lactation;

(4) It is indicated for women with asymptomatic trichomoniasis associated with endocervicitis, or cervical erosion and also for their asymptomatic sexual partners;

(5) It is very beneficial in amoebic liver abscess;

(6) When it is approved for anaerobic infections it should probably be reserved for serious infections and those unresponsive to other agents;

(7) It is of great value in CNS infections and endocarditis due to anaerobes; and

(8) As a number of treatments are available for prophylactic use, metronidazole should not be used for that purpose.

Inpharma, No. **261**, 17 (Nov. 80)

REGULATORY NEWS

Foreign collaboration ban on certain drugs

The Government has banned foreign collaboration, financial as well as technical, initially in 22 categories of industries where indigenous technology is sufficiently available. The drugs and pharmaceuticals covered under this ban are:

Caffeine (natural), phenylbutazone, Tolbutamide, Paracetamol, Phenacetin, Senna extract, Diosgenin, Clofibrate, 4-Hydroxycoumarin, Xanthotoxin, Calcium gluconate, Choline chloride, Glyceryl Glucolate, Phenylethyl biguanidine hydrobromide, Niacinamide, Ortholoyl biguanidine, Colchicine, Diazepam, Sorbitol from dextrose monohydrate, berberine hydrochloride, Belladona, Acriflavine, Calcium hypophosphate and Chlordiazepoxide.

Bengal Chemicals take-over bill passed

Bengal Chemicals and Pharmaceuticals take-over bill was passed by Lok Sabha on 20th November with a few official amendments. Union Petroleum and Chemicals Minister, Mr. P. C. Sethi who piloted the bill said, while replying on the debate, that concrete steps would be taken up for modernisation and diversification of the company after streamlining its management and production.

The management of the company was taken over in December, 1977 under the Industries (Development and Regulation) Act. A compensation of Rs. 5.2 crores has been paid and an other company Smith Stanistreet has been appointed custodian of the BCPW till such time as Government decides to vest the undertaking in an existing company or new Government firm.

Erythromycin to be banned

According to a circular addressed by the Drugs Controller of India, the semi-synthetic antibiotic erythromycin may be banned soon. A panel of medical experts, constituted by the Drugs Controller, has recommended that neither the solid dosage form nor paediatric doses of erythromycin estolate should be allowed to be marketed. However, oral erythromycin products containing erythromycin base, erythromycin stearate or erythromycin ethylsuccinate would be allowed to remain in market as they are useful drugs.

Doubts about its adverse effects had arisen when Anti-Infective Agents advisory committee of US Food and Drug Administration found that administration of erythromycin estolate induces an allergic type of chloestatic hepatitis. Since there were some other side-effects also, a warning was to be included in all the labelling of this product. But now US FDA has reviewed it and found that erythromycin estolate is unsafe in adults because of its hepatotoxicity. So it is contemplating its removal. But other safer oral erythromycin products are not affected by this.

Indian action is consequential to US FDA action.

Severe penalty for licence non-utilization

The Union Government is considering adopting severe penalty clauses to check non-utilization of industrial licences by private firms, according to Union Minister of State for Industries, Mr. Charanjit Chanana. This non-utilization of licences usually leads to artificial shortages of the commodities. He further stated that henceforth, licences would be given only to those who give an undertaking for the time bound promotion of ancillaries.

Streptomycin sulphate, chloramphenicol powder and palmitate prices fixed

According to a notification issued by the Ministry of Petroleum, Chemicals & Fertilizers, pooled prices of Streptomycin sulphate, Chloramphenicol powder and Chloramphenicol palmitate have been fixed at Rs. 660.75, Rs. 622 and Rs. 806 per kg respectively. However, the retention price for streptomycin sulphate manufactured by Ms/ Synbiotics Ltd. is Rs. 429 and Rs 660.75 for all other units making the same. Similarly Chloramphenicol powder produced ex-benzaldehyde has a retention price of Rs. 644/kg and for production ex-L-base it is Rs. 622/kg. Chloramphenicol palmitate has a retention price of Rs. 679.50/kg.

Vitamin content: Drug units given more time

Drug manufacturers have now been given time till December 31, 1980 to comply with the requirements regarding the maximum and minimum limits of vitamins in patent or proprietary medicines. This is the sixth extension of time given by Drugs Controller of India.

Stability data for thermolabile products required

Drug Control Authorities have advised all the manufacturers of thermolabile products to carry out stability studies for their products. It is reported that due to lack of stability data the products are, in many cases, not of standard quality.

The authorities have made it clear that unless such stability data are received, permission to manufacture additional products containing thermolabile drugs will not be granted to self manufacturers or on behalf of loan licencees.

Liquid oral preparations to be packed in plastic containers

The Drugs Consultative Committee has taken a decision that the manufacturers, of liquid preparations should be advised to use the plastic containers for packing their liquid oral preparations with the following conditions:

(1) The plastic containers used for packing of liquid oral preparations should be of polyethylene only. No other classes of plastics should be permitted to be used for packing of liquid oral preparations.

(2) The polyethylene containers used should comply with the ISI specifications. The manufacturers who use the plastic containers should take a certificate from the manufacturer of the containers that they have been tested and conform to ISI specifications.

(3) The Drugs Control Administration should grant permission for packing liquid oral preparations in polyethylene containers along with data in regards to the compatability of the container vis-a-vis the content.

Human pharmaceuticals containing sulphanilamide and sulphathiazole banned

The Drugs Controller of India has proposed that production of formulations containing sulphanilamide and sulphathiazole be discontinued.

The two drugs can, however, be produced as intermediates for the manufacture of other sulpha drugs or for veterinary use.

Drug price equalisation account to be operational soon

Union Government has decided to start a drug prices equalisation account under which benefits of using low priced bulk drugs for formulation production will be used to help other units using high cost ones. This move is being implemented under the Drugs (Prices Control) Order 1979 which states that where a manufacturer of formulations utilises in his formulations a bulk drug, either from his own production or procured by him from any other source, the price of which is lower than the price allowed to him in the calculations of the price of his formulations, the Government may require such a manufacturer to deposit into the Drug Prices Equilisation account the excess amount so determined.

This move is going to help the units operating under high costs and will average out the prices.

Ban proposed on benzene use in toys

The European Economic Community has proposed a ban on the use of benzene in toys because of its possible link to cancer in humans. This highly toxic chemical is widely used in the manufacturing of toys particularly balloons.

20 more countries join WHO pharmaceutical certification scheme

With the recent addition of 20 more countries, the WHO "Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce", the total number of participating countries has risen to 58. The additional 20 countries are: Angola, Bahrain, Bolivia, Burma, Chile, Costa Rica, Ethiopia, Ghana, Guatemala, Guyana, Mauritania, Mozambique, Nigeria, Pakistan, Panama, Rwanda, Sao Tome and Principe, Turkey, Yugoslavia and Zambia.

Scrip, No. **544,** 12 (26 Nov. 80)

Bismuth salt products to carry warning labels

Because of the reported neurological disturbances, drug products containing bismuth salts will now have a new warning label in Austria and West Germany. The following warning must be printed on the labels:

> "Should not be used for long periods or in high dosage without medical advice"

The average recommended daily dose for such products is 0.6 to 0.8 gm. Doctors have been told to observe patients undergoing this treatment for any adverse effect.

International Drug Regulatory Monitor, No. **90,** 21 (Nov. 80)

US FDA issues guidelines for human leukocytes collection

Bureau of Biologics of the US Food and Drug Administration has prepared guidelines for the collection of human leukocytes for further manufacturing use—primarily for the production of interferon. The guidelines are based on a review of available data concerning maximum frequency and total number of leukocyte collections obtained by various methods, such as, leukapheresis, whole blood collections and double plasmapheresis procedures. Copies can be had from: FDA, Room No. 4-62, 5600 Fishers Lane, Rockville MD 20857, USA.

Scrip, No. **530,** 7 (8 Oct. 80)

Chile, W. Germany, Italy ban methapyrilene products

Chile's Ministry of Health, Italy's Ministero della Sanita and West Germany's Bundesgesunheitsamt have proposed to remove methapyrilene containing products from their respective countries.

These moves follow the US National Cancer Institute's report that laboratory animals had developed liver cancer due to methapyrilene.

International Drug Regulatory Monitor, No. **90,** 21 (Nov. 80)

Alclofenac and other drug products withdrawn in Italy

Following the action initiated by the Italian Ministry of Health, many drug products have been ordered to be withdrawn or carry a label warning. The actions initiated are:

(1) Chlormadinone acetate has been withdrawn because of increased incidence of breast tumours in experimental animals in long term toxicity tests.

(2) Alclofenac, a non-steroidal anti-inflammatory, has been withdrawn because of the reports that its epoxide urinary metabolite has mutagenic activity.

(3) Products containing boric acid or its salts or its derivatives should have the following warning label:

> "Accidental ingestion or use of this product for prolonged periods or in excessive dosage can result in toxic reactions. To be kept away from children. Not to be used in children under 3 years of age".

(4) All preparations containing urethane have been withdrawn because of carcinogenic potential.

(5) Noramidopyrine for intravenous or intramuscular injections, containing more than 1 gm/vial has been withdrawn.

(6) Estrogen-progestogen containing products must carry the following label warning:

"Indicated only when considered absolutely necessary in the treatment of menopausal symptoms. To be used exclusively under close medical surveillance because of possible thrombogenic and carcinogenic activity".

International Drug Regulatory Monitor, No. **89,** 17 (Oct. 80)

Yemen bans many drugs

Yemen Arab Republic's drug regulatory agency, the Supreme Board of Drugs, has issued regulatory guidelines about many drugs. The following drugs have been withdrawn or banned in the country:

(1) All preparations containing phenacetin.

(2) All preparations containing aminophenazone.

(3) All preparations containing phenformin because of fatal lactic acidosis.

(4) Ban on the use of estrogen-progestogen products for the pregnancy testing. Package inserts must carry the contraindication.

(5) All preparations of phenolphtha lein to be withdrawn because of the reports of overuse-induced potassium loss and intestinal atonia in France.

International Drug Regulatory Monitor, No. **89,** 17 (Oct. 80)

US FDA proposes inclusion of a warning in menstrual tampons

The US Food and Drug Administration has issued a warning that is required to be included in the labelling of menstrual tampons. It warns users of toxic shock syndrom (TSS), a rare but serious and sometimes fatal disease, associated with the use of tampons. The proposed warning statement would advice tampons users-how they could almost entirely eliminate or greatly reduce the risk of TSS. It would also advice the users of the steps to be taken if the symptoms of the disease appear.

Following is the text of the warning to be included in the labelling:

"Warning: Toxic Shock Syndrom is a rare but serious disease that can occur in menstruating women. TSS can cause death. The disease has been associated with the use of tampons. You may, therefore, want to consider not using tampons, or alternating tampons with napkins.

If you develop high fever and vomiting or diarrhoea during your menstrual period, you should remove your tampon immediately and talk to a physician".

International Drug Regulatory Monitor, No. **90,** 22 (Nov. 80)

Moisturization labelling for skin care products in France

The French Ministry of Health has issued a rule regarding "moisturization" claims of skin care products. The ministry wants the following guidelines to be followed for all such products:

(1) On the labels and in advertisements, "moisturizing" may be used to qualify a superficial action on the stratum corneum by a cosmetic, provided the text explains this action, i. e., how the water is retained or concentrated in the superficial layers of the skin.

(2) "Super moisturizing", "remoisturizing" etc. may not be used.

(3) If the product has a deeper action (deeper than the stratum corneum) the product will come under the category "Products other than Medicine" or "Medicine" as the case may be and will require a special permit.

International Drug Regulatory Monitor No. **90,** 21 (Nov. 80)

FDA may revise reserpine labelling

The US Food and Drug Administration, after studying the statement of US National Cancer Institute that reserpine containing drugs cause cancer in laboratory rats and mice, is contemplating a revision in the labelling of all such drugs.

The revision will advise the physicians of this finding that three different kinds of cancer are produced in test animals given reserpine in feed for 103 weeks, these are the cancers of the adrenal gland in male rats, the mammary gland in female mice and of the seminal vesicles in male mice.

Scrip, No. **528,** 8 (1 Oct. 80)

WHO contemplating provision of essential drug list to all

UNICEF, World Bank and WHO are discussing an ambitious scheme under which a selected list of about 20 essential drugs will be provided to all in need as part of national strategies of health for all, based on primary health care, according to Dr. H. Mahler, WHO Director-General. Dr. Mahler, who addressed the 31st session of WHO Regional Committee for the Western Pacific held in Manila, explained that this list included drugs for most of the diseases of major public health importance encountered in primary health care.

Scrip, No. **533,** 10 (20 Oct. 80)

New GMP regulations implemented

Japanese Ministry of Health and Welfare have promulgated fresh "Standards for the Manufacture and Quality Control of Drugs" (GMP) according to which software i. e. technical control of GMP shall be regulated by these newly issued regulations. Hardware (structures and equipment) shall be controlled by the regulations under the 'Structure and Equipment of Pharmaceutical Premises'.

These new regulations also carry the following proposals: (1) Drug manufacturing supervisor shall supervise the manufacturing control manager and quality control manager, (2) Pharmaceutical testing shall in principle be conducted by manufacturer but under exceptional cricumstances by other laboratories.

Japan Medical Gazette, **17,** 1 (20 Oct. 80)

DRUGS & PHARMACEUTICALS INDUSTRY: IN PARLIAMENT

This section aims to highlight the proceedings of the winter session of the Lok Sabha and Rajya Sabha relevant to Drugs & Pharmaceuticals industry.

Fall in Production of Life Saving Drugs

Question No. 241. SHRI V. KISHORE CHANDRA S. DEO (RAJYA SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state:

(*a*) Whether it is a fact that the production of life-saving drugs has fallen considerably during the current year 1980;

(*b*) if so, the reasons thereof; and

(*c*) the steps taken by the Government to meet the requirements during the current year and the measures to be taken to meet the long-term demand?

The Minister of State for Petroleum, Chemicals & Fertilizers:

Answer: (*a*), (*b*) & (*c*): There has been some shortfall in the production of certain life-saving bulk drugs during the current year (April-September 1980) as compared to the corresponding period last year. The shortfall in production is reportedly due to a number of reasons, such as, water and power problems, labour unrest, limited availability/non-availability of some raw materials (like Ethyl Acetate, Calcium Chloride, Benzene etc.) and of packing raw materials, equipment breakdown in some units, escalations in the cost of inputs etc.

Government monitor the production of life-saving bulk drugs. In specific cases of constraints in production brought to its notice, Government take remedial measures to the extent possible, as for instance (*i*) in respect of non-availability of packing materials, Government reduced Customs duty on the import of aluminium foil and allowed its liberal imports by including it under OGL; (*ii*) Government arranged needed imports of canalised bulk drugs to supplement indigenous production; (*iii*) a more liberal policy of distribution of canalised drug items has been put into effect; (*iv*) applications for industrial licence/registration letters are cleared on expeditious basis; and (*v*) Government have decided the procedure to be followed for giving price adjustments for bulk drugs and have already revised the price of some essential bulk drugs based on the reports of the Bureau of Industrial Costs and Prices which take into account the escalation in the cost of inputs due to the hike in petroleum prices in 1979.

Issue of Industrial Licences to Organised Sector Units

Question No. 1086. PROF. RAMLAL PARIKH (RAJYA SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state:

(*a*) what facilities in the matter of industrial licensing and in the release of canalised raw materials are being extended to the organised sector units located in the backward districts, under new Drug Policy; and

(*b*) in what manner the facilities are proposed to be improved in the near future?

The Minister of State for Petroleum, Chemicals & Fertilizers:

Answer: (*a*) & (*b*): Government have announced, from time to time, a number of concessions and facilities for the industrial development of backward areas. These include concessional finance extended by central term-lending institutions, subsidy on fixed capital investment, income tax reliefs, transport subsidy, etc. The incentives and assistance rendered to such units are also contained in Chapters VI and VII of the Guidelines for Industries published by the Department of Industrial Development. Since none of these facilities is exclusive to drug industry, no mention has been made of these in the New Drug Policy Statement.

I. D. P. L. Canalised Bulk Drugs

Question No. 1087. PROF. RAMLAL PARIKH (RAJYA SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state:

(*a*) the basis on which all canalised bulk drugs produced by the Indian Drugs and Pharmaceuticals Limited were taken into distribution pool at their declared prices whereas, similar facility was refused to other Indian companies; and

(*b*) the details of the declared/approved prices of the canalised drugs, their import prices and their pooled prices from the inception of the price control order?

The Minister of State for Petroleum, Chemicals & Fertilizers:

Answer: (*a*) There are only three canalised bulk drugs, namely, Streptomycin, Tetracycline and VitaminB2 which are produced by Indian Drugs and Pharmaceuticals Ltd. and are presently distributed by the State Chemicals and Pharmaceutical Corporation of India Ltd. at pooled prices. In case of these three bulk drugs indigenous prices have been fixed by the Government on the basis of recommendations of the Bureau of Industrial Costs and Prices. Similar arrangements also exist in respect of other canalised items like Chloramphenicol Powder, Chloramphenicol Palmitate, and Chloroquin Phosphate produced by units other than Indian Drugs and Pharmaceuticals Ltd.

(*b*) A statement showing the present indigenous prices, import prices and pooled prices of canalised bulk drugs distributed by the State Chemicals & Pharmaceutical Corporation of India Ltd., is as follows:

Sl. No.	Name of the drug	Indigenous price approved by the Government Rs./kg.	Import price during 1979-80 (weighted average cif price) Rs./kg.	Pooled price if any Rs./kg.
1.	Amoxicillin	Nil	896.62	Nil
2.	Chloramphenicol Powder	644.00 ex basic production 622.00 ex-L-base production	357.73	622.00
3.	Chloramphenicol Palmitate	679.50	400.24	806.00
4.	Chloroquin Phosphate	342 for captive use 352 for sale to others	276.66	428.00
5.	Doxy cycline	Nil	1374.28	Nil
6.	Erythromycin base	1789 for captive use 1872 for sale to others	Nil	Nil
7.	Erythromycin Stearate	1006.00 ex TIOC)ex basic 1706.00 for captive use)produc- 1785.00 for sale to others) tion	1041.54	Nil
8.	Erythromycin Estolate	1625.00 for captive use 1700.00 for sale to others	Nil	Nil
9.	Ethambutol	Nil	334.94	Nil
10.	Gentamycin Sulphate	Nil	12612.53	Nil
11.	Griseofulvin	—	724.24	—
12.	Indomethacin	918.70	Nil	Nil
13.	Methyl Dopa	Nil	517.05	Nil
14.	Streptomycin Sulphate	429 for Synbiotics 660.75 for others	376.50	660.75
15.	Sulphamethoxazole	601.52	242.08	Nil
16.	Tetracycline base/HCL	650.00	256.82	650.00
17.	Trimethoprim	2587.00	505.28	Nil
18.	Vitamin B1	749.71 (oral grade) 789.20 (Ampoule grade) 770.80 (Mononitrate)	258.62	Nil
19.	Vitamin B2	1417.95	449.77	1100.00
20.	Vitamin C	104 Sarabhai 128 Jayant	78.51	Nil
21.	Ampicillin Trihydrate	1391.68 }	698.03	Nil
22.	Ampicillin Anhydrous	1952.76 }		Nil

Revised Prices of Drugs

Question No. 1120 N. P. CHENGALRAYA NAIDU (RAJYA SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state:

(*a*) whether the Bureau of Industrial Costs and Prices has completed the excercise of computing the new prices of drugs;

(*b*) if so, how for these prices are meeting the demands of the drug industry; and

(*c*) what steps are envisaged to look into the demands of the drug industry?

The Minister of State for Petroleum, Chemicals & Fertilizers:

Answer: (*a*) Bureau of Industrial Costs and Prices have worked out the prices of a number of bulk drugs whose prices are controlled under Drugs (Prices Control) Order, 1979 and sent their reports to this Ministry.

(*b*) & (*c*) The prices determined by the Bureau of Industrial Costs and Prices are fair prices worked out in accordance with the procedure approved by the Government. There is no general complaint that the prices determined are not fair. However, if any representation is received from any manufacturer against the price fixed by the Government on the basis of the recommendations of the Bureau of Industrial Costs and Prices, the same is examined on merits.

Production of bulk drugs by Pfizer and Dumex

Question No. 1141. SHRI MANUBHAI PATEL (RAJYA SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state:

(*a*) the quantity and value of bulk drugs and formulations produced by M/s Pfizer and Dumex during the last three years; import content in each of the bulk drugs and ex-factory value of production;

(*b*) the bulk drugs and formulations which these companies are producing in excess of their licensed capacity and excess production in terms of quantity and value; and

(*c*) whether it is a fact that DGTD had asked for the details of ex-factory value of production of several bulk drugs from these two companies and whether the information has been furnished?

The Minister of State for Petroleum, Chemicals & Fertilizers:

Answer: (*a*) The name of M/s Dumex was changed to M/s Pfizer in July, 1961. The requisite information in respect of M/s Pfizer for the three years 1976, 1977 &

1978 is furnished in Annexure-I. Information for 1979 is not readily available. The import of the bulk drugs based on production during the year 1976-77 (period ending 30th November), as reported by M/s Pfizer are given in Annexure-II.

(*b*) M/s Pfizer have been found to be producing bulk drugs viz. Tetracyclines, Chlorpropamide, Banminth and Protein Hydrolysate in excess of their licensed capacities. The information relating to licensed capacity of each of the bulk drugs and production thereof by M/s Pfizer during the years 1976, 1977 and 1978 is furnished in Annexure-I referred to in part (*a*) above.

Similar information in regard to formulations is not available because the Industrial Approvals accorded to M/s Pfizer for the manufacture of formulations do not specify item-wise annual capacities. However, this issue forms the part of the exercise relating to the consolidation of the Industrial Licences.

(*c*) Yes, Sir.

ANNEXURE-I

Name	Unit	Licensed Capacity	Production (Value in Rs/lakhs)					
			1976		1977		1978	
			Quantity	Value	Quantity	Value	Quantity	Value
1	2	3	4	5	6	7	8	9
BULK DRUGS								
Chlorpropamide	Tonnes	6.5	7.98	11.36	7.988	14.93	7.882	13.91
PAS & its Salts	,,	110	106.51	66.57	97.686	75.47	89.802	70.57
Isonicotinic Acid Hydrazine (INH)	,,	80	56.84	87.16	34.004	68.98	44.712	87.59
Tetracyclines	,,	14	46.26	443.85	49.828	306.47	52.065	314.46
Banminth	,,	0.3	0.375	2.64	0.203	1.48	0.547	3.06
Protein Hydrolysate	,,	110	239.70	53.79	231.593	45.77	268.883	49.96
FORMULATIONS								
Injectables			*Qty.*		*Qty.*		*Qty.*	
Liquid Parenterals	Litres	Not fixed	1,62,778	3181 lakhs	1,81,711	1653.27	2,11,318	2025.07
Dry Fills	No. in Million vials		22.20		11.56		16.33	
Tablets & Capsules	No. in Million		705.54		640.71		844.28	
Liquid	Litres		5,36,695		4,78,352		6,03,158	
Solids	Kilograms		5,83,381		5,59,510		6,70,451	
Ointments	Kilograms		88,909		84,793		1,01,096	

Note : Similar information in respect of the year 1979 is not readily available.

ANNEXURE-II

Sl. No.	Name of the Bulk Drugs	Import content/kg. (CIF) in Rs.
1	2	3
1.	Chlorpropamide	35.89
2.	PAS and its Salts	0.19
3.	Isonicotinic Acid Hydrazine (INH)	NIL
4.	Tetracyclines	28.47 (for Tetracycline) 51.97 (for Oxytetracycline)
5.	Banminth	96.54
6.	Protein Hydrolysate	NIL

Decision to allow Multinationals to manufacture Drugs

Question No. 317. SHRI NARAYAN CHOUBEY (LOK SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state:

(*a*) whether Government have decided to allow multinationals to manufacture certain drugs;

(*b*) if so, the details thereof;

(*c*) whether this decision is a departure from the 1978 policy on drugs; and

(*d*) if so, the details and reasons for changing the policy?

The Minister of Petroleum, Chemicals & Fertilizers:

Answer: (*a*) & (*b*): Drug Policy with regard to multinational companies having more than 40% foreign equity (such companies being known as FERA companies or foreign companies also) is contained in paras 13-26 of the statement which was laid on the Table of the Lok Sabha on 29th March, 1978. If a multinational or foreign company statisfies the provisions of the new drug policy, it is granted the Letter of Intent/Industrial Licence.

During 1980 (January-September), five Letters of Intent have been granted to the following foreign companies:

S. No.	Name	Letter of Intent No.	Item of manufacture
1.	M/s. Abbott Labs. (I) Pvt. Ltd.	LI: 324 (80) dt. 26.7.80	1. Diethyl Malonate 2. Pentothal Sodium 3. Nembutal Sodium 4. Metformin 5. Chloroquin Phosphate 6. Substituted Melonic esters (except N-Butyl Malonate).
2.	M/s. Ciba Geigy of India Ltd.	LI: 455 (80) dt. 30.8.80	1. Trimethoprim 2. Formulation of Trimethoprim.
3.	M/s. Pfizer Ltd.	LI: 383 (80) dt. 21.8.80	1. Morantel Tartrate 2. Pyrantel Pamoate 3. Formulations of the two drugs specified above.
4.	M/s. E. Merck (I) Pvt. Ltd.	LI: 476 (80) dt. 22.9.80	1. Vitamin K1 (Butyl Menadione) 2. Vitamin K4 (Butyrate) 3. Vitamin K4 (Sodium Phosphate) 4. Vitamin K4 (Diacetate) 5. Vitamin K3.
5.	—do—	LI: 478 (80) dt. 23.9.80	Vitamin 'E' and its derivatives.

No Industrial Licence has, however, been granted to any foreign company during the period January-September 1980.

(*c*): The Drug Policy as referred to against (*a*) and (*b*) above is still being followed in the examination of Industrial Licence applications from foreign companies.

(*d*): Does not arise.

Rise in Prices of Essential Drugs

Question No. 1008 SHRI AMARSINGH RATHAWA (LOK SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state:

The steps Government are considering to take to bring the prices of essential drugs down and to make these medicines easily available?

The Minister of State for Petroleum, Chemicals & Fertilizers:

Answer: Prices of essential and life saving drug formulations specified in the Drugs (Prices Control) Order 1979 and of the bulk drugs required for these formulations are controlled. However, keeping in view the escalation in the cost of inputs mainly due to the increase in the prices of petroleum products, Government have decided to allow price adjustments in the price-controlled bulk drugs and formulations, on the basis of the cost studies of the Bureau of Industrial Costs and Prices. These price adjustments would result in the increases in prices of some drugs and formulations and reduction in cases of other drugs and formulations.

Revision of Policy for Regularisation of Drug Production

Question No. 1040. SHRIMATI GEETA MUKHERJEE (LOK SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state:

(*a*) what was the specific reason for the reversal of the Government policy of not regularising the production of drugs by foreign companies beyond their licensed capacity or the highest production in 1977 or 1978 or whichever is higher;

(*b*) is it a fact that the spokesman of the foreign drug companies—the OPPI—submitted a memorandum to Government prior to this decision; and

(*c*) if so, what were the points raised in that memorandum?

The Minister of Petroleum, Chemicals & Fertilizers:

Answer: (*a*) The question of the implications of Government's decision regarding recognition of installed capacities in excess of licensed capacities announced by the Department of Industrial Development in August, 1980 with specific reference to the decision of regularisation of excess production over the licensed capacities under the drug policy of 1978, is being examined in consultation with the concerned departments.

(*b*) The O.P.P.I. submitted a Memorandum dated 2.6.1980 to the Government.

(*c*) The major points raised in the Memorandum have already been laid on the Table of the House in reply to parts (*a*) and (*c*) to (*f*) of Unstarred Question No. 6016 for 29th July, 1980.

Shortage of Essential Drugs in Metropolitan Cities

Question No. 1076. DR. SARADISH ROY (LOK SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state:

(*a*) whether Government are aware that the essential drugs needed for delivery and post-delivery cases, high blood pressure, hypertension, leprosy and dysentery are totally non-available in Delhi, Calcutta, Madras and Bombay; and

(*b*) if so, steps taken by Government in this matter?

The Minister of State for Petroleum, Chemicals & Fertilizers:

Answer: (*a*) No, Sir, However, shortage of some specific brand formulations needed for delivery and post-delivery cases, high blood pressure, hypertension, leprosy and dysentery were reported periodically from among the four Metropolitan Cities of Delhi, Calcutta, Madras and Bombay.

(*b*) Government monitor the availability of life saving and essential formulations every week. Remedial action to relieve shortage is taken by telegraphically advising the manufacturers of specific brands reported in shortage and the manufacturers of the equivalent products also to rush supplies to the places from where shortages were reported.

Decision to Raise Prices of Essential Drugs

Question No. 1119. SHRI MADHAV RAO SCINDIA (LOK SABHA):

Will the Minister of Petroleum & Chemicals be pleased to state:

(*a*) whether on the basis of cost studies undertaken by the Bureau of Industrial Costs and Prices, a decision has been taken by Government to revise and raise the prices of certain essential drugs; if so, from which date the increase has been allowed;

(*b*) the details of the decision taken and the results of the study made by the Bureau, indicating drug-wise the increase in the cost of production and the price increase allowed; and

(*c*) whether in anticipation of the increase in prices these drugs went out of market and kept back by many manufacturers?

Minister of State for Petroleum. Chemicals & Fertilizers:

Answer: (*a*) & (*b*) Government have in August 1980, approved the procedure for allowing price adjustments of price controlled drugs under Drugs (Price Control) Order, 1979 on the basis of cost studies by the Bureau of Industrial Costs and Prices. In pursuance of this decision, Government have, so far, announced the revised prices of 14 bulk drugs. A Statement showing the increases in prices in respect of these 14 bulk drugs which take into consideration the increases in their cost of production and the date from which the revised prices come into force, is as below:

Sl. No.	Name of the Drug	Price per kg. before revision (Rupees)	Revised price per kg. (Rupees)	Date of revision
1.	Pethidine HCl.	1050.00	1522.24	17-9-1980
2.	Phthalyl Sulphathiazole	173.00	188.55	27-9-1980
3.	Acetazolamide	350.00	564.56	4-10-1980
4.	Ephedrine HCl.	405.00	487.56	4-10-1980
5.	Folic Acid	2497.07 (for captive use) 2536.40 (for sale to others)	2631.62	4-10-1980
6.	Sulphacetamide	102.25	172.97	4-10-1980
7.	Sulphacetamide Sodium	102.25	113.10	4-10-1980
8.	Sulphadimidine	161.41	178.56	4-10-1980
9.	Chloramphenicol Sodium Succinate	No Price was fixed for indigenous production.	1024.45	4-10-1980
10.	Streptomycin Sulphate	475.00 (Pooled)	660.75 (Pooled)	6-10-1980
11.	Chloramphenicol Powder	460.00 (Pooled)	622.00 (Pooled)	7-10-1980
12.	Chloramphenicol Palmitate	460.00 (Pooled)	806.00 (Pooled)	7-10-1980
13.	Procaine Hydrochloride	114.00	158.83	9-10-1980
14.	Vitamin B2	935.48 (Pooled)	1100.00 (Pooled)	13-11-1980

(*c*) The price adjustments will not be increases alone. There will be increases as well as decreases. There are a number of reasons for shortfall in the availability of a few drugs. However, no instances of any essential drugs being kept out of market due to anticipated price increase have come to the notice of Government.

Revision in Prices of Bulk Drugs

Question No. 1110. SHRI S. M. KRISHNA (LOK SABHA):

Will the Minister of Petroleum & Chemicals be pleased to state:

(*a*) whether confusion prevails in the drug industry after the recent notification issued by his Ministry revising prices of 13 essential bulk drugs;

(*b*) whether his Ministry has not announced leader prices for formulations based on these drugs; and

(*c*) the manner in which his Ministry proposes to deal with the situation and see that these essential drugs are made available in the market at the prices fixed by Government?

The Minister of State for Petroleum, Chemicals & Fertilizers:

Answer: (*a*) Government are not aware of any confusion prevailing in the drug industry after the price-revision of the essential bulk drugs allowed recently.

(*b*) The revised leader prices of formulations based on some of the bulk drugs whose prices have been revised, would be announced shortly.

(*c*) Whenever it comes to the notice of the Government that any manufacturer is marketing any drug at prices other than the authorised prices, show-cause notices are issued to such manufacturers and/or the concerned State Drug Controllers are requested to investigate and take necessary action.

Industrial licences pending for finalizations

Question No. 1145. SHRI MANUBHAI PATEL (RAJYA SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state :

(*a*) the number of industrial licences or other approvals pending finalisation—Indian, foreign and small scale company-wise;

(*b*) the number of show-cause notices issued to M/s Pfizer for violations of Government rules and the final decision taken in those cases, if any;

(*c*) the number of items which are of doubtful validity marketed by M/s Pfizer on which basis canalised raw materials are procured by them; and

(*d*) the manner in which Government propose to proceed against this company?

The Minister of State for Petroleum, Chemicals & Fertilizers:

Answer : (*a*) As on 31.10.80 28 applications from Indian companies and 34 applications from foreign companies for grant of Industrial Licences were pending finalisation. Besides it, three (one from foreign company and two from Indian companies) requests for grant of One-Time Permission to manufacture certain drugs for export purposes are also pending finalisation. No such information about small-scale companies is readily available.

(*b*) : Three show-cause notices were issued to M/s. Pfizer Ltd. Present position of these cases is as follows :

(*i*) The first show-cause notice was issued to the company concerning discharge of export obligation and execution of export bond on the 7th May, 1976. From the documents made available by Pfizer, it was observed that the company had discharged their export obligation and therefore, no further action was called for.

(*ii*) The second show-cause notice issued to Pfizer on 4th April, 1977 was concerning manufacture of Protinex without authorisation under Industries (Development and Regulation) Act, 1951. Ministry of Law, Justice and Company Affairs on consideration of the reply of the company, advised against prosecution and stoppage of production of Protinex. The advice of Law Ministry was accepted and, therefore, no further action was called for.

(*iii*) The third show-cause notice issued to M/s. Pfizer on 5th April, 1977 concerned marketing of Protinex without price approval under Drugs (Prices Control) Order, 1970. Law Ministry have held that since Protein Hydrolysate which is the main ingredient of Protinex, is not a bulk drug within the meaning of the Drugs (Prices Control) Order, 1970, Protinex would not squarely fall within the definition of a formulation. In this view, it was doubtful whether Protinex would come within the purview of the Drugs (Prices Control) Order, 1970. As such no action could be taken against the firm. However, under Drugs (Prices Control) Order, 1979, formulation has been defined so as to include items like Protinex, in case such items are manufactured on the basis of a licence under the Drugs and Cosmetics Act, 1940. Attention of M/s. Pfizer Ltd. has been drawn to the said definition and they have been advised to apply for price approval under the 1979 Order.

(*c*) & (*d*) : The position in respect of unauthorised items of manufacture being marketed by the company would be known only after a final view is taken on the claims of the company in this regard.

Manufacture of Life-Saving Drugs

Question No. 1152. SHRI SYED SHAHABUDDIN (RAJYA SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state:

(*a*) whether Government have a standing machinery to monitor the availability of life saving drugs and pharmaceuticals in the open market;

(*b*) whether there is any proposal to canalise the imports of such items through a centralised agency, if not manufactured in the country;

(*c*) whether Government have a long term plan to make the country self-sufficient in respect of such items through manufacture within the country on licence or royalty basis; and

(*d*) if so, what is the response of the foreign manufacturers in this regard?

The Minister of State for Petroleum, Chemical & Fertilizers:

Answer: (*a*) Government monitors the availability of life-saving and essential drugs in the open market based on the reports received from the State Drugs Controller and Zonal offices of the Central Drugs Standard Control Organisation.

(*b*) Certain essential bulk drugs as specified in Appendix 9 of the Import Policy are imported through the State Chemicals and Pharmaceuticals Corporation of India. These include some of the life-saving and essential bulk drugs not manufactured in the country.

(*c*) & (*d*) : The Working Group on Drugs and Pharmaceuticals constituted by the Planning Commission has estimated the demand of essential bulk drugs for the plan period of 1980-81 to 1984-85 and arrived at the requirements of such drugs. Licensing of bulk drugs in the Organised Sector is guided by these estimates. Applications from Indian, including public sector companies, and foreign companies for grant of industrial licence are received and considered within the framework of the New Drug Policy. Some industrial licenses to such companies have been granted while others are at different stages of consideration. The ultimate aim is to manufacture the country's demand within the country to the maximum extent possible.

Foreign Technology Procured by IDPL

Question No. 1181. SHRI C. CHINNASWAMY (LOK SABHA):

Will the Minister of Petroleum, Chemicals & Fertilizers be pleased to state :

(*a*) details about foreign technologies procured by I.D.P.L. for different drugs;

(*b*) the names of the countries from which purchased; and

(*c*) is there any proposal under consideration to develop I.D.P.L more effectively?

The Minister of State for Petroleum, Chemicals & Fertilizers:

Anwer: (*a*) & (*b*) : Details are as listed below:

Foreign Collaboration and Name of Country

Year	Brief particulars of collaborations involving technical collaborations only	Total value	Name of the country and the firm with which collaboration has been entered into
4th June, 1976	For the supply of know-how alongwith detailed design engineering for the production of Doxycycline Hyclate.	U.S. $ 0.5 lakhs	M/s Farmafin, Italy M/s I.C.L., Italy
6th Dec., 1976	For the supply of know-how, high yielding strains with detailed design engineering for the production of :	U.S. $ 4 lakhs	I.C.L. Plant (Italy)
	(*i*) Potassium Penicillin		
	(*ii*) Tetracycline Hcl.	U.S. $ 3 lakhs	Archifar-Plant (Italy)
	(*iii*) Erythromycin Hyclate, & technical know-how with detailed design	U.S. $ 3 lakhs	Archifar-Plant (Italy)
	(*iv*) Semi-synthetic Penicillins	U.S. $ 5 lakhs	I.C.L. Plant (Italy)
29th June, 1976	For the supply of technical know-how and some equipments for the production of Methyl Ethyl Pyridine, Niacin and Nicotinamide	20,00,000 Swedish Kr. and 14.36 Million Swedish Kr.	M/s A. B. Bofors, Sweden and M/s Lonza, Switzerland.

(*c*) : I.D.P.L. has R & D centres in the Antibiotics Plant at Rishikesh and Synthetic Drugs Plant at Hyderabad. Originally as a part of the technical and financial association with Technoexport, Moscow, I.D.P.L. had obtained technology for 15 drugs. I.D.P.L. developed technology for 30 drugs which are under commercial production. R & D efforts are being made to generate technology for known drugs and also new drugs. I.D.P.L. has also plans for expansion for the manufacture of various drugs.

INDUSTRIAL LICENCES AND LETTERS OF INTENT

ISSUED DURING SEPTEMBER, 1980

Sl. No.	Name and Address of the Industrial Undertaking	Article of Manufacture	Annual Capacity	Type of Licence, No. and date
	Licences			
1.	German Remedies Ltd., Shiv Sagar Estate, 'A' Block Dr. Annie Besant Road, Worli, Bombay-18.	Normacol Granules	50 tonnes (exis.) 200 tonnes (after expn.)	Substantial Expansion CIL: 255/80 Dated: 22.9.80.
2.	Indian Drugs & Pharmaceuticals Ltd., Complex Dundahera, Delhi-Gurgaon Road, Gurgaon, Haryana.	(*i*) Sulphamethoxazole	8 tonnes (exis.) 30 tonnes (after expn.)	Substantial Expansion/ New Article CIL: 258/80 Dated: 22.9.80.
		(*ii*) Formulation in the form of suspension (paediatric syrup based on Sulphamethoxazole and Trimethoprim)	25 kilo litre	
3.	Paranjpe Engineering & Foundry Co. Ltd., Bhosari Industrial Area, Pune.	(*i*) Theophylline and Aminophylline	60 tonnes	New Unit CIL: 268/80 Dated: 22.9.80.
		(*ii*) Synthetic Caffeine	40 tonnes	
		(*iii*) Acetic Acid (By product)	200 tonnes	
4.	Raptakos Brett & Co. Ltd., 47 Dr. Annie Besant Road, Worli, Bombay-400 018.	(*i*) Pheniramine maleate	2 tonnes	New Article CIL: 248/80 Dated: 10.9.80.
		(*ii*) Chlorpheniramine maleate	2 tonnes	
		(*iii*) 5-5-Disphenyl hydantoin	2 tonnes	
		(*iv*) dl-Panthenol		
		(*v*) Calcium dl-Pantothenate	12 tonnes	

Contd.

Sl. No.	Name and address of the Industrial Undertaking	Article of Manufacture	Annual Capacity	Type of Licence, No. and date
5.	Uni-Sankyo Ltd., No. 5-9-24/81, Shapurwadi, Hyderabad,	Sporlac bulk drug	215 kgs	COB IL: 66/80 Dated: 18.9.80.
	Letters of Intent			
1.	Ambalal Sarabhai Enterprises (P) Ltd., (Division: Sarabhai M. Chemicals), Gorwa Road, Baroda	Choline and its salts	50 tonnes (after expn.)	Substantial Expansion IL 462/80 Dated: 11.9.80.
2.	Shri C. G. Amin, Alembic Chemical Works, Alembc Road Baroda	(*i*) Doxycycline capsules (*ii*) Amoxycillin capsules BP (*iii*) Amoxycillin Dry Syrup	1665 kgs 16574 kgs 3630 kgs	New Article LI: 499/80 Dated: 30.9.80.
3.	E. Merck (India) Pvt. Ltd., Shivsagar Estate, 'A' Block, Dr. A. B. Road, Worli, Bombay-18.	(*i*) Vitamin K1 (Butyl Menadione) (*ii*) Vitamin K4 (Butyrate) (*iii*) Vitamin K4 (Sodium Phosphate)	250 kgs 400 kgs 150 kgs	New Article LI: 476/80 Dated: 22.9.80.
		(*iv*) Vitamin K4 (Diacetate) (*v*) Vitamin K3 Vitamin 'E' and its derivatives	200 kg 380 kg 34 tonnes (after expn.)	LI: 478/80 Dated: 28.9.80
4.	Managing Director, Gujarat Indl. Investment Corp. Ltd., 4th Floor, Natraj Chambers, Ashram Road, Ahmedabad.	Chloroquine and its salts	150 tonnes	New Units LI: 542/80 Dated: 30.9.80.

Sl. No.	Name and Address of the Industrial Undertaking	Article of Manufacture	Annual Capacity	Type of Licence, No. and date
5.	Suhrid Geigy Ltd., Post Box No. 48, Wadi Wadi, Baroda	(*i*) Trimethoprim	2 tonnes	New Article LI: 466/80 Dated: 11.9.80.
		(*ii*) Sulphamethoxazole	10 tonnes	
		(*iii*) Formulations of Trimethoprim and Sulphamethoxazole	One tonne of Trimethoprim and 5 tonnes of Sulphamethoxazole in terms of bulk drug.	
6.	Tamil Nadu Dadha Pharmaceuticals Ltd., 10 Jeypore Nagar, Madras.	*Items of Manufacture :* 1. Artisid Suppositories 2. Ethambutol Tablets 3. Vitamin B1, B6, B12 Tablets 4. Sodium PAS Granules 5. Nitrofurazone Dusting Powder 6. Zinc Cream 7. Dexamethasone Injection 8. Zinc Sulphate Capsules		New Article LI: 533/80
		Bulk drugs involved		
		Indomethacin	300 kg	
		Ethambutol	1000 kg	
		Thiamine Mononitrate	1560 kg	
		Pyridoxine Hydrocholoride	2760 kg	
		Cyanocobalamine	4 kg	
		Sodium Amino salicylate	8000 kg	
		Nitrofurazone	30 kg	
		Zinc Oxide	16798 kg	
		Dexamethasone	2.85 kg	
		Zinc Sulphate	528 kg	

NEW PRODUCTS

(*Source:* Inpharma)

Sl. No.	Generic Name	Trade Name	Manufacturer	Country
1.	*Analgesic*			
	Diflunisal	Dolobid	Merck Sharp & Dohme	New Zealand
	Naproxen sodium	Anaprox	Syntex	USA
	Zomepirac	Zomax	Johnson & Johnson	USA
2.	*Antiandrogenic/Contraceptive*			
	Cyproterone+ethinyl estradiol	Diane	Schering AG	S. Africa
3.	*Antianginal*			
	Nifedipine	Adalat	Bayer	New Zealand
4.	*Antianxiety*			
	Ketazolam	Solatran	Beecham	Switzerlnad/ W. Germany
5.	*Antiarrhythmic*			
	Propafenone	Rythmonorm	Knoll	Hong Kong
6.	*Antibacterial*			
	Cefaclor	Ceelor	Lilly	New Zealand
	Cinoxacin	Cinobac	Lilly	Switzerland
	Fosfomycin	Fosfocin	Boehringer Mannheim	W. Germany
	Fosfomycin	Fosfocin	Crinos	Italy
	Netilmicin	Netilmicin	BYK-Essex	W. Germany
	Netilmicin	Netilyn	Schering-Plough	Portugal
	Piperacillin	Pipril	Cyanamid	W. Germany
	Pivmecillinam	Selexid	Leo	New Zealand
	Trimethoprim+sulfamoxole (Co-trifamole)	Co-Fram	Abbott	UK

Sl. No.	Generic Name	Trade Name	Manufacturer	Country
7.	*Antidepressant*			
	Butriptyline	Evadyne	Ayerst	Hong Kong
8.	*Antidiarrhoeal*			
	Difenoxin + atropine	Lyspafen	Protea	Australia
9.	*Antifungal*			
	Clotrimazole	Gyne-Lotremin Lotremin	Schering Corp Schering Corp	Hong Kong
10.	*Antihistamine*			
	Azatadine maleate	Zadine	Schering Corp	Hong Kong
11.	*Antihyperlipidemic*			
	Bezafibrate	Bezalip	Boehringer Mannheim	Hong Kong
12.	*Anti-inflammatory*			
	Choline magnesium trisalicylate	Trilisate	Napp	UK
	Diclofenac	Voltaren	Geigy	Canada
	Indomethacin	Mobilan	Galen	UK
	Tiaprofenic acid	Surgam	Roussel	W. Germany
13.	*Antiviral*			
	Vidarabine	Vira-A	Parke-Davis	S. Africa
14.	*β-Blocker*			
	Metipranolol	Disorat	Boehringer Mannheim	Hong Kong
	Nadolol	Corgard	Squibb	Italy
15.	*β-Blocker/diuretic*			
	Metipranolol+ butizide	Torrat	Boehringer Mannheim	Hong Kong
16.	*Bronchodilator*			
	Ipratropium	Atrovent	Boehringer Ingelheim	Hong Kong
17.	*Diuretic*			
	Chlorothiazide	Azide	Fawns & McAllan	Australia
	Piretanide	Arelix	Hoechst	Italy

Contd.

Sl. No.	Generic Name	Trade Name	Manufacturer	Country
18.	*Estrogen*			
	Estriol	Ovestin	Organon	Australia
19.	*Estrogen/progestogen*			
	Norethindrone (norethisterone) +ethinylestradiol	Oestro-Primolut	Schering AG	W. Germany
20.	*Hypnotic*			
	Temazepam	Euhypnos Normison	Sigma Wyeth	Australia/ New Zealand
	Triazolam	Halcion	Upjohn	W. Germany
21.	*Gallstone dissolving agent*			
	Chenodeoxycholic acid	Chenofalk	Armour	UK
	Ursodeoxycholic acid	Ursofalk	Dr Falk	Hong Kong
22.	*Topical anti-inflammatory*			
	Budesonide	Budesonide	Astra	W. Germany
	Bufexamac	Co-Rectaid	Lederle	Australia
23.	*Topical Corticosteroid*			
	Diflorasone Diacetate	Florone	Upjohn	Switzerland

MONOGRAPHS RECOMMENDED TO BE INCLUDED IN THE 3rd EDITION OF INDIAN PHARMACOPOEIA

Indian Pharmacopoeia, whose revised 3rd edition is under prepartion is to made more exhaustive by the inclusion of a large number of new monographs. Following is the list, arranged in alphabetical order:

1. Aluminium Sulphate
2. Amantadine Hydrochloride
3. Amantadine Hydrochloride Capsules
4. Amantadine Hydrochloride Syrup
5. Aminocaproic Acid
6. Aminocaproic Acid Injection
7. Aminocaproic Acid Tablets
8. Ampicillin Mixture
9. Anti-coagulant Citrate Dextrose Solution
10. Anti-coagulant Sodium Citrate Solution
11. Atropine Mithonitrate
12. Bacitracin Zinc
13. Bendrofluazide
14. Benzalkonium Chloride Solution
15. Berberine Chloride
16. Betamethasone 17 Valerate
17. Bethanidine Sulphate
18. Bethanidine Tablets
19. Bisacodyl
20. Bisacodyl Tablets
21. Butylated Hydroxyanisole
22. Butylated Hydroxytoluene
23. Calcuim Levulinate
24. Calcium Levulinate Injection
25. Calcium Pantothenate
26. Carbenicillin Disodium
27. Carbenicillin Injection
28. Carbimaxole
29. Cellulose Acetate Phthalate
30. Cephalexin
31. Cephalexin Capsule
32. Cephalexin Tablets
33. Chloramphenicol Eye Ointment
34. Chloramphenicol Sodium Succinate
35. Chloramphenicol Sodium Succinate Injection
36. Chloroquin Phosphate Injection
37. Chlorphenesin
38. Cholecalciferol
39. Citric Acid (Anhydrous)
40. Clonidine Hydrochloride
41. Clonidine Tablets
42. Cycloserine
43. Cyproheptadine Hydrochloride
44. Cyproheptadine Hydrochloride Tablets
45. Cyproheptadine Hydrochloride Syrup
46. Dehyroemetine Hydrochloride
47. Dehydroemetine Injection
48. Deslanoside
49. Deslanoside Injection
50. Dequalinium Chloride
51. Diazepam Injection
52. Diethyltoluamide
53. Dimethisterone
54. Diphenylpyraline Hydrochloride
55. Diphenoxylate Hydrochloride
56. Doxycycline Hydrochloride
57. Doxycyline Capsule
58. Edetate Disodium
59. Ethacrynic Acid
60. Ethacrynic Acid Tablets
61. Ethionamide
62. Ethionamide Tablets

63. Ethopropazine Hydrochloride
64. Ethopropazine Tablets
65. Ethosuximide
66. Ethyloestrenol
67. Ethyloetsrenol Tablets
68. Fenfluramine Hydrochloride
69. Fenfluramine Tablets
70. Fludrocortisone Acetate
71. Fludrocortisone Tablets
72. Fluphenazine Hydrochloride
73. Fluphenazine Hydrochloride Injection
74. Fluphenazine Tablets
75. Frusemide Injection
76. Furazolidone
77. Glibenclamide
78. Glibenclamide Tablets
79. Glyceryl Monostearate
80. Griseofulvin
81. Griseofulvin Tablets
82. Hydralazine Hydrochloride
83. Hydroxyethyl Theophylline
84. Ibuprofen
85. Ibuprofen Tablets
86. Idoxoridine
87. Indomethacin
88. Indomethacin Capsules
89. Isocarboxazid
90. Isocarboxazid Tablets
91. Isoprenaline Hydrochloride
92. Isoprenaline Hydrochloride Injection
93. Isosorbide Dinitrate
94. Isoxsuprine Hydrochloride.
95. Kanamycin Sulphate
96. Kanamycin Sulphate Injection
97. Lanatoside C
98. Lanatoside C Tablets
99. Levodopa
100. Levodopa Capsules
101. Levodopa Tablets
102. Lincomycin Hydrochloride
103. Lincomycin Capsules
104. Lithium Carbonate
105. Lithium Carbonate Tablets
106. Lynoestrenol
107. Lysine Hydrochloride
108. Magnesium Stearate
109. Mannitol
110. Megestrol Acetate
111. Mercaptopurine
112. Mestranol
113. Methandienone
114. Methandienone Tablets
115. Methdilazine Hydrochloride
116. Methotrexate
117. Methotrexate Tablets
118. Methylergometrine Injection
119. Methylergometrine Maleate
120. Methylergometrine Tablets
121. Nalidixic Acid
122. Nalidixic Acid Tablets
123. Nandrolone Decanoate
124. Nandrolone Decanoate Injection
125. Nandrolone Phenylpropionate
126. Naphazoline Nitrate
127. Niclosamide
128. Niclosamide Tablets
129. Nitrofurantoin
130. Nitrofurazone
131. Norethisterone
132. Norethisterone Tablets
133. Noscapine
134. Nystatin
135. Nystatin Tablets
136. Oxprenolol Hydrochloride
137. Oxprenolol Tablets
138. Oxytetracycline eye Ointment
139. D-Panthenol
140. Benzathine Penicillin Injection
141. Fortified Benzathine Penicillin injection
142. Pentamidine Isothionate
143. Pentazocine Hydrochloride
144. Phenformin Hydrochloride
145. Phenformin Tablets
146. Phentolamine Hydrochloride
147. Phentolamine Mesylate
148. Phenylbutazone
149. Phenylephrine Hydrochloride

150. Phenylmercuric Aceate
151. Phenytoin Injection
152. Pholcodine
153. Piperazine Hydrate
154. Polyethylene Glycol 1500
155. Polyethylene Glycol 4000
156. Polyethylene Glycol 6000
157. Polysorbate 20
158. Polysorbate 80
159. Polyvinylpyrrolidone
160. Pralidoxime Chloride
161. Pralidoxime Chloride Injection
162. Primaquine Phosphate
163. Primaquine Phosphate Tablets
164. Prochlorperazine Injection
165. Prochlorperazine Maleate
166. Prochlorperazine Mesylate
167. Prochlorperazine Tablets
168. Promethazine Theoclate
169. Propantheline Bromide
170. Propoxyphene Hydrochloride
171, Propoxyphene Napsylate
172. Propyl Gallate
173. Propylene Glycol
174. Pyrazinamide
175. Pyrazinamide Tablets
176. Riboflavine Phosphate Sodium
177. Rifampicin
178. Salbutamol Sulphate
179. Salbutamol Tablets
180. Scoplaminc Hydrobromide
181. Scopolamine Hydrobromide Tablets
182. Shellac
183. Sodium Ascorbate
184. Sodium Carboxymethyl Cellulose
185. Sodium Cromoglycate
186. Sodium Cromoglycate Cartridges (through special inhaler)
187. Sodium Lactate Injection
188. Sorbitol
189. Sorbitol Solution
190. Spiranolactone
191. Stilbestrol Diphosphate
192. Succinylcholine Chloride
193. Tartaric Acid
194. Tetramisole Hydrochloride
195. Thiabendazole
196. Thiabendazole Tablets
197. Thiomersal
198. Titanium Dioxide
199. Tragacanth
200. Triamcinolone
201. Triamcinolone Acetonide
202. Triamcinolone Tablets
203. Triamterene
204. Triamterene Capsule
205. Trifluperazine Hydrochloride
206. Triflupromazine Hydrochloride
207. Vanillin
208. Verapamil Hydrochloride
209. Verapamil Injection
210. Verapamil Tablets
211. Vitamin E Acetate
212. Yeast Dried

Copies of these draft monographs are available for perusal at the following offices:—

1. The Drugs Controller (India),
   Directorate General of Health Services,
   Nirman Bhavan, N. Delhi
2. Shri A. D. Nadkarni,
   Senior Scientific Officer,
   Drugs Control Laboratory,
   C/o Office of the Commissioner,
   Food & Drug Administration, Maharashtra
   Griha Nirman Bhavan, Bandra (E),
   Bombay 400 051.
3. Office of the Dy. Drugs Controller (India),
   South Zone, Thousand Lights, Madras—6.
4. Office of the Dy. Drugs Controller (India),
   East Zone, 233/4, Lower Circular Road,
   Calcutta 700 020.

LIST OF ITEMS TO BE RETAINED IN I. P. 3rd EDITION

It has been proposed to retain the following 285 monographs from the 2nd edition of pharmacopoeia. The monographs to be retained are:

1. Acetomenaphthone (Acetomenadione)
2. Acetomenaphthone Tablets
3. Acetazolamide
4. Acetazolamide Tablet
5. Adrenaline
6. Adrenaline Bitartrate
7. Adrenaline Tartrate Injection
8. Alcohol
9. Aluminium Hydroxide Gel
10. Dried Aluminium Hydroxide Gel
11. Aminophylline
12. Aminophylline Injection
13. Aminophylline Tablet
14. Ammonium Chloride
15. Amodiaquine Hydrochloride
16. Amodiaquine Tablet
17. Amylobarbitone
18. Amylobarbitone Tablet
19. Amylobarbitone Sodium
20. Amylobarbitone Sodium Tablet
21. Antazoline Hydrochloride
22. Antazoline Hydrochloride Tablet
23. Arachis oil
24. Ascorbic acid
25. Ascorbic acid Injection
26. Ascorbic acid Tablets
27. Aspirin
28. Atropine Sulphate
29. Atropine Sulphate Injection
30. Atropine Sulphate Tablets
31. Atropine eye Ointment
32. Bacitracin
33. Barium Sulphate
34. Barium Sulphate for Suspension
35. White Beeswax
36. Yellow Beeswax
37. Benzocaine
38. Benzoic acid
39. Benzyl Alcohol
40. Benzyl Benzoate
41. Benzyl Benzoate application
42. Boric acid
43. Busulphan
44. Busulphan Tablets
45. Caffeine
46. Calamine
47. Calcium Aminosalicylate
48. Calcium Aminosalicylate Tablets
49. Calcium Carbonate
50. Calcium Chloride
51. Calcium Gluconate
52. Calcium Gluconate Injection
53. Calcium Gluconate Tablets
54. Calcium Hydroxide
55. Calcium Lactate
56. Calcium Lactate Tablets
57. Dibasic Calcium Phosphate
58. Tribasic Calcium Phosphate
59. Castor Oil
60. Cetosterol Alcohol
61. Cetrimide
62. Chloral Hydrate
63. Chloramphenicol
64. Chlorbutol
65. Chlorcyclazine Hydrochloride
66. Chlorcyclazine Tablets
67. Ergocalciferal (Calciferol) Vit. D2
69. Ethyl Alcohol
69. Oleic acid

70. Oxytetragcline HCl
71. Oxytocin Injection
72. Hard *P*araffin
73. Light Liquid Paraffin
74. Liquid Paraffin
75. White Soft Paraffin
76. Yellow Soft Paraffin
77. Paraldehyde
78. Paramethadione
79. Saccharin
80. Saccharin Sodium
81. Salicylic acid
82. Senna Fruit
83. Senna leaf
84. Shark liver oil
85. Dilute Shark oil
86. Shark liver oil with vitamin D
87. Silver Nitrate
88. Sodium Antimony Gluconate
89. Sodium Antimony Gluconate Injection
90. Sodium Chloride
91. Compound Sodium Chloride Solution
92. Sodium Citrate
93. Sodium Citrate Anticoagulant
94. Sodium Hydroxide
95. Compound Sodium Lactate Injection
96. Sodium Salicylate
97. Sodium Thiosulphate
98. Starch
99. Streptomycin Sulphate
100. Streptomycin Injection
101. Streptomycin Tablets
102. Sucrose
103. Succinylsulphathiazole
104. Succinylsulphathiazole Tablets
105. Sulphacetamide Sodium
106. Sulphacetamidc Eye Ointment
107. Sulphadiazine
108. Sulphadiazine Tablets
109. Sulphadimidine
110. Sulphadimidine Tablets
111. Sulphadimidine Sodium
112. Sulphadimidine Injection
113. Sulphafurazole
114. Sulphafurazole Tablets
115. Sulphobromophthalein Sodium
116. Sulphobromophthalein Sodium Injection
117. Talc
118. Testosterone Propionate
119. Testosterone Propionate Injection
120. Tetrachloroethylene
121. Tetracycline Hydrochloride
122. Tetracycline Capsules
123. Tetracycline Injection
124. Tetracycline Tablets
125. Theophylline
126. Thiamine Hydrochloride
127. Thiamine Hydrochloride Injection
128. Thiamine Hydrochloride Tablets
129. Thiamine Mononitratc
130. Thiopentone Sodium
131. Thiopentone Injection
132. Thymol
133. Thyroid
134. Thyroid Tablets
135. Thyroxine Sodium
136. Thyroxine Tablets
137. Tolazoline Hydrochloride
138. Tolazoline Tablets
139. Tolbutamide
140. Tolbutamide Tablets
141. Trichloroethylene
142. Tripelennamine Hydrochloride
143. Tripelennamine Tablets
144. Troxidone
145. Troxidone Capsules
146. Tubocurarine Chloride
147. Tubocurarine Injection
148. Undecylenic Acid
149. Urea
150. Vasopressin Injection
151. Vitamins 'A' and 'D' Capsules
152. Concentrated Vitamin 'A' Solution
153. Concentrated Vitamin 'D' Solution
154. Concentrated Vitamins 'A' and 'D' Solution

155. Purified Water
156. Water for Injection
157. Sterile Water for Injection
158. Zinc Oxide
159. Zinc Stearate
160. Zinc Sulphate
161. Zinc Undecylenate
162. Zinc Undecylenate Ointment
163. Allopurinol
164. Allopurinol Tablets
165. Aluminium Hydroxide Tablets
166. Amitriptyline Hydrochloride
167. Amitriptyline Tablets
168. Ampicillin
169. Ampicillin Trihydrate
170. Ampicillin Capsules
171. Ampicillin Sodium
172. Ampicillin Injection
173. Analgin
174. Analgin Tablets
175. Bephenium Hydroxynaphthoate
176. Bephenium Hydroxynaphthoate Granules
177. Betamethasone
178. Betamethasone Tablets
179. Betamethasone Sodium Phosphate
180. Betamethasone Sodium Phosphate Injection
181. Betamethasone Sodium Phosphate Tablets
182. Human Normal Serum Albumin Injection
183. Human Normal Immunoglobulin Injection
184. Carbamazepine
185. Carbamazepine Tablets
186. Cephaloridine
187. Cephaloridine Injections
188. Chloramphenicol Capsules
189. Chloramphenicol Palmitate
190. Chloramphenicol Palmitate Oral Suspension
191. Chlordiazepoxide
192. Chlordiazepoxide Tablets
193. Chloroquine Sulphate
194. Chloroquine Sulphate Tablets
195. Chloroquine Sulphate Injection
196. Chlorpheniramine Maleate
197. Chlorpheniramine Tablets
198. Chlorpropamide
199. Chlorpropamide Tablets
200. Chlorthalidone
201. Chlorthalidone Tablets
202. Clofibrate
203. Clofibrate Capsules
204. Cloxacillin Sodium
205. Cloxacillin Capsules
206. Cloxacillin Injection
207. Cyclophosphamide
208. Cyclophosphamide Injection
209. Cyclophosphamide Tablets
210. Demethylchlortetracycline Hydrochloride
211. Demethylchlortetracycline Capsules
212. Dexamethasone
213. Dexamethasone Tablets
214. Dexamethasone Sodium Phosphate
215. Dexamethasone Sodium Phosphate Injection
216. Dextran 40 Injection
217. Dextran 110 Injection
218. Diazepam
219. Diazepam Capsules
220. Diazepam Tablets
221. Diiodohydroxyquinoline Tablets
222. Diloxanide Furoate
223. Diloxanide Furoate Tablets
224. Erythromycin Estolate
225. Erythromycin Estolate Tablets
226. Erythromycin Stearate
227. Erythromycin Stearate Tablets
228. Ethambutol Hydrochloride
229. Ethambutol Tablets
230. Ferrous Fumarate
231. Ferrous Fumarate Tablets
232. Frusemide
233. Frusemide Tablets
234. Gentamicin Sulphate

235. Gentamicin Injection
236. Guanethidine Sulphate
237. Guanethidine Tablets
238. Hydrochlorothiazide
239. Hydrochlorothiazide Tablets
240. Hydroxocobalamin
241. Hydroxocobalamin Injection
242. Imipramine Hydrochloride
243. Imipramine Tablets
244. Iron Dextran Injection
245. Methyldopa
246. Methyldopa Tablets
247. Metronidazole
248. Metronidazole Tablets
249. Nicoumalone
250. Nicoumalone Tablets
251. Oxyphenbutazone
252. Oxyphenbutazone Tablets
253. Oxyphenonium Bromide
254. Oxyphenonium Bromide Tablets
255. Oxytetracycline
256. Oxytetracycline Injection
257. Paracetamol
258. Paracetamol Tablets
259. Pheniramine Maleate
260. Pheniramine Tablets
261. Phenobarbitone
262. Phenobarbitone Tablets
263. Piperazine Adipate
264. Piperazine Adipate Tablets
265. Piperazine Phosphate
266. Piperazine Phosphate Tablets
267. Propranolol Hydrochloride
268. Propranolol Tablets
269. Quiniodochlor Tablets
270. Sodium Aminosalicylate Granules
271. Sodium Aurothiomalate
272. Sodium Aurothiomalate Injection
273. Sodium Chloride and Dextrose Injection
274. Sulphadimethoxine
275. Sulphadimethoxine Tablets
276. Sulphamethoxazole
277. Sulphaphenazole
278. Sulphaphenazole Tablets
279. Tetracycline
280. Tetracycline Eye Ointment
281. Thiacetazone
282. Thiacetazone and Isoniazed Tablets
283. Trimethoprim
284. Trimethoprim and Sulphamethoxazole Tablets
285. Vitamin A

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